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SPINAL ALIGNMENT APPARATUS AND METHODS

Abstract:

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(A1) Spinal alignment apparatus includes bodies which connect to vertebra to be aligned, and elongated elements that connect to the bodies. The elements are adjustable relative to the bodies in multiple dimensions, with locking mechanisms that allow the alignment to proceed in an orderly fashion until a desired degree of correction is achieved. Each elongated element has a shaped end terminating in the first portion of the lockable coupling mechanism. The vertebral connector bodies each include a feature for attaching the body to a respective vertebrae, and the second portion of the lockable coupling mechanism. The feature for attaching the body to a respective vertebrae may include a pedicle screw or, alternatively, a shape such as a hook adapted for sublaminar engagement. The elongated element also preferably includes a length adjustment mechanism, such as a telescoping or threaded section to provide a desired length in conjunction with a desired degree of alignment. Various coupling mechanisms are disclosed to provide multiple degrees of freedom prior to fixation.

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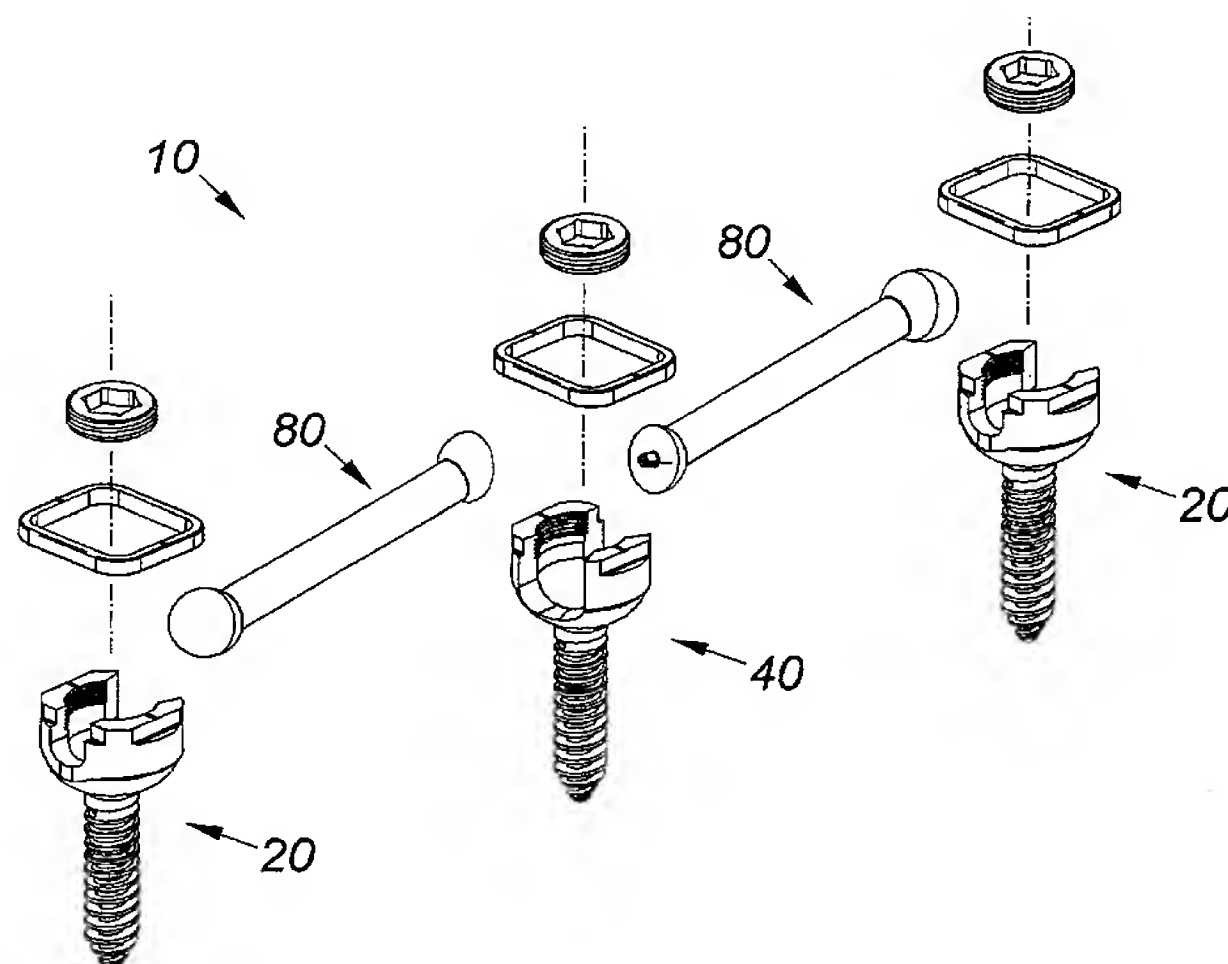
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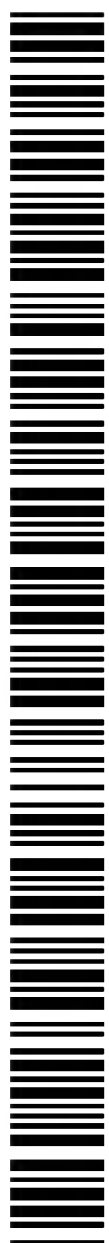
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(54) Title: SPINAL ALIGNMENT APPARATUS AND METHODS



(57) **Abstract:** Spinal alignment apparatus includes bodies which connect to vertebra to be aligned, and elongated elements that connect to the bodies. The elements are adjustable relative to the bodies in multiple dimensions, with locking mechanisms that allow the alignment to proceed in an orderly fashion until a desired degree of correction is achieved. Each elongated element has a shaped end terminating in the first portion of the lockable coupling mechanism. The vertebral connector bodies each include a feature for attaching the body to a respective vertebrae, and the second portion of the lockable coupling mechanism. The feature for attaching the body to a respective vertebrae may include a pedicle screw or, alternatively, a shape such as a hook adapted for sublaminar engagement. The elongated element also preferably includes a length adjustment mechanism, such as a telescoping or threaded section to provide a desired length in conjunction with a desired degree of alignment. Various coupling mechanisms are disclosed to provide multiple degrees of freedom prior to fixation.



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SPINAL ALIGNMENT APPARATUS AND METHODS

Field of the Invention

This invention relates generally to instrumentation, tools and techniques associated with spinal fixation and, in particular, to apparatus and methods facilitating spinal correction in multiple dimensions.

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Background of the Invention

The human spine exhibits some degree of curvature at different levels to facilitate normal physiologic function. Correction may be required when this curvature deviates substantially. A common problem is lateral deviation of the spine, commonly termed scoliosis.

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Spinal deformity occurs when a patient has abnormal frontal or sagittal plane alignment. At the same time, the cervical and lumbar spine exhibit lordosis, while the thoracic spine has kyphosis. Thus, when performing spinal fusion, surgeons may be required to preserve or restore both front plane and sagittal alignment while taking lordosis and kyphosis into account.

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As discussed in U.S. Patent No. 5,540,689, the first successful internal fixation method for surgically treating scoliosis used the Harrington instrumentation system. According to this technique, a rigid rod with hooks at each end is implanted adjacent the concave side of the scoliotic spine. The spine is manually straightened to a desired extent and a distraction rod is used to maintain the correction by exerting vertical
20 forces at each end. The rod commonly has a ratcheted end over which hooks are slidably mounted and locked in place. To accommodate lordosis, a compression rod is sometimes placed on

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the convex side of the scoliotic spine.

The Harrington instrumentation system has been used successfully for some time, but because the distraction rod is fixed to the spine in only two places, failure at either end causes the entire system to fail. Another deficiency with existing mechanisms and approaches is that the single rod used to correct the defects must be contoured to fit various attachment sites. In patients having compound spinal deformity, this may be extremely difficult. A further problem is that the contoured rod frequently limits further correction of certain types of deformities. That is, once the rod is in position, further correction of the deformity is difficult, since existing systems tend to limit incremental alignment procedures.

An alternative treatment has since evolved which takes advantage of segmented fixation. According to this method, a rod is fixed to the spine at multiple points by means of a sublaminar wires which run underneath the lamina of the vertebra and around the rod. The use of multiple fixation sites enhances stability and reduces the need for additional post-operative bracing.

Sublaminar fixation utilizing current devices has two primary weaknesses, however. First, the wires are simply wrapped around the rod, resulting in a rod to cable junction which is not rigid. Second, the thin wires can cut in some instances right through the lamina.

U.S. Patent No. 6,019,759 uses multiple longitudinal members with flat plates that attach using hooks or screws. However, the plates are stacked on top of one another at each attachment site, resulting in an overall structure that tends to be quite thick. Systems have a high sagittal profile are often thick enough to be felt through the skin. Additionally, the teachings of the '759 patent do not allow for easy correction or preservation of sagittal alignment.

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The need remains, therefore, for a system and method that allows incremental correction of spinal defects, ideally in all three dimensions.

Summary of the Invention

This invention resides in spinal alignment apparatus, including implantable
5 components, instrumentation, and methods of use. In broad and general terms, the preferred embodiment includes bodies which connect to the vertebra to be aligned, and elongated elements that connect to the bodies. The elements are preferably adjustable relative to the bodies in multiple dimensions, with locking mechanisms that allow the alignment to proceed in an orderly fashion until a desired degree of
10 correction is achieved.

Each rigid, elongated element has at least one end terminating in the first portion of the lockable coupling mechanism. The vertebral connector bodies each include a feature for attaching the body to a respective vertebrae, and the second portion of the lockable coupling mechanism. This arrangement permits the elongated
15 elements to be adjusted in multiple dimensions relative to a given connector body prior to being lockingly coupled thereto.

The feature for attaching the body to its respective vertebrae may include a pedicle screw or, alternatively, a shape such as a hook adapted for sublaminar engagement. The elongated elements may also preferably include a length adjustment
20 mechanism, such as a telescoping or threaded section, to provide a desired length in conjunction with a desired degree of alignment.

Various coupling mechanisms are disclosed to provide multiple degrees of freedom prior to fixation. In the preferred embodiment, the mechanism includes a fixed or adjustable-length rod having ball-shaped ends coupled to a vertebral

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connector providing multiple degrees of freedom before being locked into position once a desired orientation is achieved.

Brief Description of the Drawings

FIGURE 1A is a frontal view of elongated rods and hooks currently used to
5 correct spinal defects;

FIGURE 1B shows the use of two rods in place, attached to multiple vertebrae;

FIGURE 1C illustrates the way in which a typical prior-art hook is positioned under the spinal lamina for rod insertion;

10 FIGURE 2A is a frontal view of basic instrumentation according to the invention utilizing elongated members in the form of links of different length as opposed to longer rods;

FIGURE 2B shows the instrumentation of Figure 2A in place relative to multiple vertebrae;

15 FIGURE 3A illustrates components associated with a preferred embodiment of the invention, including a one- and multiple-opening pedicle screws, compound rods, tightening bands, and fasteners;

FIGURE 3B is a detail drawing of a single-opening pedicle screw according to the invention;

20 FIGURE 3C is a top-down view of the single-opening pedicle screw of Figure 3B;

FIGURE 3D is a detail drawing of a multi-opening pedicle screw according to the invention;

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FIGURE 3E is a top-down view of the multi-opening pedicle screw of Figure 3D;

FIGURE 3F is a drawing that shows a preferred set-screw fastener according to the invention for use with the single- and multi-opening fasteners of Figures 3A
5 through 3E;

FIGURE 3G is a drawing which shows the way in which caps may be added to elongated members according to the invention to produce spherical or semi-spherical endings;

FIGURE 3H is a drawing which shows the way in which multiple elongated
10 members may be interconnected to produce a single spherical or semi-spherical joint region;

FIGURE 3I illustrates components associated with an alternative embodiment of the invention, including a pedicle screw, swivel connector and locking links;

FIGURE 3J illustrates an embodiment of the invention similar to that depicted
15 in Figure 3I, but wherein the pedicle screw includes a threaded end as opposed to a ball-end-socket type of connection;

FIGURE 3K is a side view of a preferred transverse connector according to the invention;

FIGURE 3L is a top view of the transverse connector of Figure 3K;

20 FIGURE 3M is a top view of the transverse connector of Figure 3K, illustrating multiple degrees of freedom made possible by the arrangement;

FIGURE 3N depicts multiple views of the preferred transverse connector of Figure 3K, showing various degrees of angulation;

FIGURE 3O illustrates the use of a ball joint which permits the preferred
25 transverse connector to accommodate non-parallel rods;

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FIGURE 3P is an end view of the preferred transverse connector used to illustrate the desirability of reduced dimensions;

FIGURE 4A illustrates a sublaminar hook according to the invention having a ball-shaped connector;

5 FIGURE 4B illustrates a sublaminar hook according to the invention having a threaded connector;

FIGURE 4C illustrates a sublaminar hook embodiment of the invention featuring two opposing spherical joints;

10 FIGURE 4D illustrates a sublaminar hook embodiment of the invention featuring a single spherical joint;

FIGURE 5A illustrates one use of cross-links according to the invention;

FIGURE 5B illustrates an alternative cross-link configuration according to the invention;

15 FIGURE 6A shows the use of clamps as part of a first step to realign vertebrae for use with at least one embodiment of the invention;

FIGURE 6B shows the vertebrae in alignment using the clamps of Figure 6A;

FIGURE 6C shows the installation of linking rods to align the vertebrae, enabling the clamps to be removed;

20 FIGURE 7A shows a first step associated with restoring frontal alignment according to the invention;

FIGURE 7B illustrates an initial application of rods to restore frontal alignment;

FIGURE 7C illustrates an intermediate rod installation;

25 FIGURE 7D illustrates a completed rod-and-connector structure to restore frontal alignment;

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FIGURE 8A illustrates a first step associated with restoring sagittal alignment;

FIGURE 8B shows two vertebrae with appropriate sagittal alignment in preparation for rod insertion;

FIGURE 8C shows the vertebrae of Figures 8A and 8B, with a linking rod in place and a tool and the tool removed;

FIGURE 9 illustrates the use of a tool used to remove a connector from a ball-tip type of pedicle screw according to the invention;

FIGURE 10 is a drawing of an alternative embodiment of the invention, wherein connectors include multiple apertures for linking bars;

FIGURE 11A shows the configuration of Figure 10 with lines indicating a desired placement of cross-members;

FIGURE 11B shows the linking members of Figures 10 and 11A with optional sublaminar cabling;

FIGURE 12A is a drawing of an alternative connector having multiple apertures for linking bars or other elements;

FIGURE 12B shows the alternative connector of Figure 12A with lines indicating one possibility for cross-linking;

FIGURE 13 is a drawing which shows the use of diagonal connectors according to the invention for use with existing rod- or plate-alignment systems;

FIGURE 14 shows diagonal connectors for use with existing rod or plate systems, but with attachment made relative to the pedicle screws as opposed to the linking members;

FIGURE 15A illustrates an alternative embodiment wherein struts are stacked over one another onto pedicle screws;

FIGURE 15B illustrates the use of cross-link member in conjunction with the embodiment of Figure 15A;

FIGURE 16 is a side-view drawing of yet a further alternative connector according to the invention wherein more space is provided to tighten and loosen
5 associated pedicle screws;

FIGURE 17 is a drawing which shows a telescoping rod that may be adapted for use with any of the embodiments described herein;

FIGURE 18A is a drawing of a sublaminar hook having swivel connectors to which the ends of the telescoping rod of Figure 17 may attach;

10 FIGURE 18B is an top-down view of the hook of Figure 18A;

FIGURE 18C is a cross-sectional view of the hook of Figure 18A;

FIGURE 19 illustrates a pedicle-screw version of the hook of Figure 18A, also including locking connectors that swivel;

FIGURE 20 is a side-view of the spine utilizing hook and pedicle-screw
15 connectors according to one embodiment of the invention;

FIGURE 21 is a top-view drawing of the spine, showing the use of cross connectors employed in an angular fashion to maximize rigidity;

FIGURE 22A is a drawing which shows the way in which a telescoping connector according to the invention is installed;

20 FIGURE 22B illustrates an intermediate adjustment procedure associated with the use of a telescoping rod according to the invention;

FIGURE 22C shows the telescoping rod locked into place once a desired level of alignment is achieved;

FIGURE 23 is a drawing of a threaded cross-connector according to the
25 invention;

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FIGURE 24 is a drawing of a telescoping rod according to the invention having an arch feature that allows placement over arched lamina;

FIGURE 25 is a cross-sectional drawing of a transverse connector according to the invention associated with a rod junction;

5 FIGURE 26A illustrates the use of a further alternative embodiment of the invention featuring a telescoping rod that engages with hooks having one or more posts;

FIGURE 26B shows the rod of Figure 26A being rotated to achieve a desired level of alignment;

10 FIGURE 26C is a close-up view of the rotation procedure;

FIGURE 27 is a drawing of an alternative connector according to invention providing the ability to vary angulation in two planes;

FIGURE 28 is an alternative connector according to the invention which also affords multiples degrees of freedom;

15 FIGURE 29A is a drawing of an alternative connector according to the invention which uses a ball and socket held in position with a threaded fastener;

FIGURE 29B shows the alternative connector of Figure 29A locked into a desired orientation;

20 FIGURE 30A is a drawing which shows an embodiment of the invention wherein a connector body and elongated element are integrally formed to achieve a low-profile interconnection scheme;

FIGURE 30B shows the configuration of Figure 30A in an assembled condition;

25 FIGURE 30C shows the way in which connector bodies having multiple male and female connectors may be joined together in succession;

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FIGURE 31A is a drawing which shows a swiveling, socket-type connector according to the invention on a body attached to a pedicle screw;

FIGURE 31B shows the arrangement of Figure 31A in an assembled condition;

5 FIGURE 31C is a series of top-down drawings illustrating the swiveling feature of the embodiments of Figures 31A and 31B;

FIGURE 32 is a drawing which shows a sublaminar hook having outward projections to receive swivel connectors;

10 FIGURE 33A is a drawing of a top-down view of a screw connector having two posts;

FIGURE 33B is a top view of a screw connector according to the invention having a single post;

FIGURE 33C is a top view of a single hook connector;

15 FIGURE 33D is an oblique drawing which shows the use of frictional surfaces to lock in the swivel action upon achieving a desired orientation;

FIGURE 33E shows how one or more manually adjustable fasteners may be added to help control rotation of a connector according to the invention;

FIGURE 34A shows how a combined longitudinal member and connector may have different lengths and angles to address different alignment situations;

20 FIGURE 34B illustrates an assembled version of an angled unit;

FIGURE 35 is a series of drawings which show a variety of longitudinal members in straight and curved configurations;

FIGURE 36A shows how a telescoping member may be assembled through a pair of nuts, then joined;

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FIGURE 36B shows a joined assembled version of the assembly of Figure 36A;

FIGURE 37 illustrates the combined use of ball-and-socket connectors and rigid link plates;

5 FIGURE 38 illustrates the overlapping of rigid link plates at different vertebral levels;

FIGURE 39 is a side view of a connector according to the invention including a cross link;

10 FIGURES 40A-40F provide different views of a central lumbar connector according to the invention;

FIGURES 41A-41G depict different views of a lumbar connector adapted to the cephalad end;

FIGURES 42A-42E show different views of a thoracic connectors according to the invention;

15 FIGURES 43A and 43B show an exploded and assembled views of sublaminar hooks with thoracic connectors attached thereto;

FIGURES 44A-44C are top views showing swiveling before and after locking into a straightened configuration;

20 FIGURE 45 is a drawing of a pedicle screw used to discuss different sizes and diameters;

FIGURE 46 is a perspective view of the pedicle screw of Figure 45 including a ball connector and link bar;

FIGURE 47 is a drawing of the configuration of Figure 46 in an assembled state;

FIGURE 48 is an assembled connector having two opposing ball-receiving sockets;

FIGURE 49 is a drawing of an exploded and assembled view of a pedicle screw having independent double connectors;

5 FIGURE 50 shows how a non-round (in this case, oval) interconnection may be used to prevent rotation of the pedicle screw relative to a connector body;

FIGURE 51 is a drawing used to introduce the use of a hinged connector according to the invention;

FIGURE 52A shows the hinge connector in an open condition;

10 FIGURE 52B shows a hinge connector locked onto a rod;

FIGURES 53A-53M illustrate the alternative use of straps according to the invention for rod movement and stabilization;

FIGURE 54 is a side view of a turnbuckle rod according to the invention;

15 FIGURE 55 is a drawing which shows the combined use of ball-and-socket connectors in criss-cross link bars;

FIGURE 56 shows how a half-washer may be used in conjunction with a nut opening that is large enough to slide over the sphere at the end of a rod;

FIGURE 57 shows an alternative use of a slotted washer permitting a nut to slide over the spherical end of a solid rod;

20 FIGURE 58A is a drawing which shows a modified connector adapted may be used to reduce impingement;

FIGURE 58B is a drawing of an anti-impingement connector utilizing a ball-and-socket arrangement;

25 FIGURES 59A and 59B are different views of a transverse connector according to the invention;

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FIGURE 60 shows the combined use of transverse connectors and hinged hooks which lock onto a solid rod;

FIGURE 61 is a close-up, end view of a hinged connector associated with an octagonal rod;

5 FIGURE 62A illustrates the use of a continuous shaped rod, in this case having a grooved cross-section;

FIGURE 62B illustrates how the modification along the rod may be interrupted according to the invention;

FIGURE 63 is a drawing which shows a bevel connector;

10 FIGURE 64 illustrates the use of multiple rods on either side of the spine;

FIGURE 65A is a drawing which shows a stabilization clamp for use with various embodiments disclosed herein;

FIGURE 65B is an end of the configuration of Figure 65A;

FIGURE 66A is a different alternative embodiment of a stabilizing assembly;

15 FIGURE 66B is a cross-section of the assembly of Figure 66A; and

FIGURE 67A-67C illustrate the use of lockable swivel-type connectors which may be fastened to one or, preferably a pair, of alignment rods to provide a desired degree of alignment and correction.

Detailed Description of the Invention

20 Figures 1A through 1C present simplified representations regarding the way in which prior-art hooks and rods are used to treat spinal deformities. Figure 1A shows a plurality of vertebrae 102 in need of alignment. In accordance with existing practice, hooks 104 are fastened to the vertebrae at points deemed to be useful by the attending surgeon. Tools are used in an attempt to align the vertebrae, at which time

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rods 106 are contoured at the time of the procedure to engage with the hooks 104 to maintain a desired degree of straightening, as shown in Figure 1B. Figure 1C illustrates the way in which a typical prior-art hook is positioned under the spinal lamina for rod insertion.

5 Figure 2A illustrates basic instrumentation according to one embodiment of the invention. As opposed to the hooks 104 of prior-art devices, rotating/swiveling connectors 204 are instead used. In addition, as opposed to the rods 106 which currently must be contoured, links 206 of varying fixed or adjustable length are coupled to the connectors, and the entire structure locked into a preferred orientation,
10 as shown in Figure 2B. Although rotating/swiveling connectors having two rod-receiving positions are shown, the preferred embodiment of Figure 3 shows how compound elements may be used for a single compression fitting and very low profile.

 Figure 3A illustrates a preferred system according to the invention, depicted
15 generally at 10. Broadly, the system includes single-opening bodies 20, multiple-opening bodies 40, and rods 80. To afford additional degrees of freedom in multiple dimensions, the invention contemplates the use of rods having ball-shaped ends as well as the flattened plates of Figures 3I and 3J. Although the ball-shaped ends are shown as joinable to permit a single compression fastener as described below, it will
20 be appreciated that solid members with integral spherical/shaped ends may be used, as well as the telescoping and other configurations disclosed with reference to the various alternative embodiments.

 Figure 3B is a detail drawing of a single-opening connector according to the invention, and Figure 3C is a top-down view of the single-opening device of Figure
25 3B. The structure 20 includes a rod-receiving body 22 coupled to a pedicle screw 24.

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The body includes one opening 23 configured for a constrained connection and a second opening 25 adapted for multiple degrees of freedom before compression fastener 28 is tightened into threaded area 30. To provide a solid mass, tension band 26 is positioned onto recesses 27 before tightening fastener 28. Figure 3C shows the
5 recesses 27 from above, as well as the bottom of hemispherical well 34 within the body 22.

Figure 3D is a detail drawing of a multiple-opening connector according to the invention, and Figure 3E is a top-down view of the multi-opening device of Figure 3D, in this case a two-port device. The structure 40 includes a rod-receiving body 42
10 coupled to a pedicle screw 44. The body includes one opening 43 configured for a first rod moveable in multiple dimensions, and a second opening 45 for a second rod, also adapted for multiple degrees of freedom before compression fastener 28 is tightened into threaded area 50. To provide a solid mass, a tension band 26 is positioned onto recesses 47 before tightening fastener 28. Figure 33 shows the
15 recesses 47 from above, as well as the bottom of the hemispherical well within the body 42. Note that in the preferred embodiment the same tightening band 26 and set screw 28 may be used for both the single- and multi-opening configurations.

Figure 3F is a cross-sectional drawing of the preferred compression fastener, in this case a set screw 28 having an allen-wrench-receiving top portion 62 and a
20 hemispherical bottom portion 64.

Figure 3G is a drawing which shows the way in which caps may be added to elongated members according to the invention to produce spherical or semi-spherical endings. Figure 3H is a drawing which shows the way in which multiple elongated members may be interconnected to produce a single spherical or semi-spherical joint
25 region. In the preferred embodiment, link members 80 have male/female half spheres

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allowing either caps or additional rods to be attached. This now only reduces the numbers of devices on the surgeon's tray, it also allows two rods to form a single ball unit for a smaller profile.

In Figure 3G, end 82 includes a male post 83, which receives end cap 84
5 having female aperture 85. The other end of the rod functions in like manner, with the male and female roles reversed. Although the posts and apertures are not technically necessary, they do allow the surgeon to pre-assemble components which hold together prior to installation, thereby maximizing the use of both hands. As shown in Figure 3H, two rods may be connected to one another as opposed to the end
10 caps, thereby allowing the fastener of Figures 3D and 3E to have rods extending from both sides. Note that the rods of Figure 3H may be turned at the joint region prior to installation, thereby permitting the rods to extend from the connector of Figures 3D and 3E at various angles prior to tightening.

Figure 3I illustrates a preferred connector system according to the invention in
15 greater detail. A pedicle screw 302 having a hemispherical head 303 is driven into the vertebrae, again, at points useful for alignment. A slot 306 may be provided to drive the pedicle screw 302 or, alternatively, a hex head or other suitable tool-engaging feature may be used.

A connector body 204 is placed over the exposed end of the screw 302 so that
20 the head 303 engages with a corresponding opening 304 in the bottom of the connector. A set screw 307 or other fastener is used to lock the body 204 in place relative to screw 302 and vertebrae to which it is attached. Note that until the devices are locked into place, the body 204 is able to swivel in three dimensions.

Link bars 206, preferably with enlarged ends are placed into recesses 308 into
25 the body 204, and these are locked into place with set screws 312 or other suitable

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fasteners. Again, until the set screws 312 are tightened down, the links 206 may have at least some play until locked into place. Although short bars 206 of equal length are illustrated, it will become apparent that the system is quite flexible, and may take advantage of bars of different or adjustable lengths and profiles. An aperture such as
5 314 may be provided to enable a tool to move the connectors into a desired position, or remove the body 204 from the screw 302, as appropriate.

Figure 3J illustrates an alternative embodiment of the invention, wherein the swivel joint between the pedicle screw and connector body is replaced with a screw 402 having a threaded end 406. The threaded end 406 now protrudes through a larger
10 hole 414 in the connector body 404, enabling a nut 407 or other suitable fastener to lock the body 404 onto the screw 402. Similar to the embodiment of Figure 3A, however, link bars 206 fit into recesses 408 in the body 404, and set screws 412, which mate with threads 410, are similarly used to lock the link bars into place once a desired orientation is achieved.

15 Figure 3K is a side view of a preferred transverse connector according to the invention. Figure 3L is a top view of the transverse connector of Figure 3K, showing how bodies 92 clamp onto rods 90. Figure 3M is a top view of the transverse connector of Figure 3K, illustrating multiple degrees of freedom made possible by the arrangement. Figure 3N depicts multiple views of the preferred transverse connector
20 of Figure 3K, showing various degrees of angulation. Figure 3o illustrates the use of a ball joint which permits the preferred transverse connector to accommodate non-parallel rods. FIGURE 3P is an end view of the preferred transverse connector used to illustrate the desirability of reduced dimensions. In particular, dimensions X and Y are both reduced according to the invention, and fastener 96 is not engaged until the
25 two halves of the unit are brought into close proximity.

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Figures 4A and 4B are drawings of improved sublaminar hooks constructed according to the invention. Broadly, these devices include bodies such as 442 having a recess such as 443 configured for engagement with sublamina, but in contrast to existing devices, either a hemispherical connector 444 or threaded connector 446 are provided on the body to engage with the inventive link connectors discussed, for example, with reference to Figures 3A and 3B. Figure 4C illustrates a sublaminar hook embodiment of the invention featuring two opposing spherical joints. Figure 4D illustrates a sublaminar hook embodiment of the invention featuring a single spherical joint.

Figures 5A and 5B illustrate, respectively, two ways in which connectors according to the invention may be cross-linked, with the understanding that additional variations are certainly possible. In Figure 5A, longer link members 502 are used to link the sides of the connector in criss-cross fashion, whereas, in Figure 5B, shorter link members 504 are used in a manner transverse to those oriented from foot-to-head along the spine. Note also that the plate and rod connectors may be used separately or together; that is while it may be advantageous to use plates at 502 and 504 for transverse interconnection, spherical joints may be preferred longitudinally along the spine, as in locations 510.

Figures 6A-6C illustrate the way in which instrumentation may be used to obtain a desired degree of vertebral correction, at which time the link members may be added to maintain the structure in correct alignment. In Figure 6A, vertebrae 610 and 620 are mal-aligned, and instruments 602 and 604 are used to adjust them into a proper orientation. Generally speaking, instrument 602 is used to urge apart the connectors shown in the left part of the drawing, where the vertebrae are too close to one another, whereas instrument 604 is used to pull the vertebrae together.

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Figure 6B is a drawing which shows a desired orientation of the connectors 612 and 622, without the vertebrae being shown, and Figure 6C illustrates how, having achieved a desired final position, link members 630 and 632 are tightened onto the connectors 612 and 622, at which time the instruments may be removed. This process is more or less repeated, on adjacent vertebral levels, until an overall desired level of alignment is achieved. Given the ease with which the link members and the connectors themselves may be readjusted, the surgeon may readily go back over areas in need of further refinement, as appropriate.

This process is shown in Figures 7A through 7D with respect to the restoration of a frontal alignment. In Figure 7A the spine is curved as shown, with seven connectors being positioned by the surgeon on the various vertebrae to begin the correction process. In Figure 7B, the connectors shown upwardly in the drawing are first brought into alignment, and in Figure 7C, cross-links and additional link members have been added further down the spine. In Figure 7D, all of the connectors are linked up, with fine adjustments being made in three dimensions, as necessary, for a desired degree of correction. Again, although two rod-receiving position are shown with respect to each body, use of the bodies and link members of Figures 3D through 3H would proceed in like fashion.

In restoring the frontal alignment just described, the manual instruments of the type shown in Figures 6A-6C would be appropriate, though they are not shown in Figures 7A-7C. To restore sagittal alignment, a different form of instrument is preferred, to raise and lower connectors as opposed to pushing and spreading. Instruments according to the invention for this purpose are shown in Figures 8A-8C. In Figure 8A, a tool 802 is inserted into connectors 804 and 806, and in Figure 8B, the

- 20 -

connectors are brought into sagittal alignment. In Figure 8C, a link member 810 is fastened to the connectors, and the tool 802 removed.

In all of the rod-receiving bodies described herein, small apertures or slots may be provided to receive a tool for corrective positioning and, with the aid of a specialized instrument such as 900 depicted in Figure 9. Using such a tool, the body may be removed from the ball-tipped hooks or pedicle screws previously described, as appropriate. Such a tool would preferably include side portions 902 and a central pin 906 which may be forced down through the opening 314 by handle 910, thereby applying force between the body and hook or screw to remove the connector for repositioning or removal.

Figure 10 is a side-view drawing of an alternative connector system according to the invention, wherein angled, preferably reinforced components 1002 are fastened to pedicle screws 1004. The members 1002 provide one or more holes, better seen in Figures 11 and 12, to which link members such as 1110 may be fastened. Note that the pieces 1102 would preferably be provided in various heights and sizes better accommodate a given patient physiology.

Figure 11A is a drawing which shows one way in which the connectors introduced with respect to Figure 10 would be used in practice. Six connectors such as 1102 are shown, each having four holes to receive link bars. With this many fastening points, multiple reinforcements may be used; in particular, both lateral and diagonal cross members are readily accommodated. Moreover, as shown in Figure 11B, the holes may be used for devices other than the link members. For example, cables 1110 may be used, where appropriate, and, in some cases, they may be wrapped around the lamina (subliminally) as depicted with numerical reference 1112.

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Rigid link members and cables may also be used with the alternative connector 1202 of Figure 12A, which includes holes 1204 on one side for link bars and additional holes 1206 on the other side for cables. Figure 12B shows the alternative connector of Figure 12A in use, with a combination of cables 1216 and
5 rigid link members 1214 (shown as lines) being used to establish a stable, cross-coupled structure.

Figure 13 illustrates an alternative arrangement according to the invention, wherein cables 1302 are applied to an existing rod/plate system to impart further structural integrity. Four diagonally oriented cable paths are used, though more or
10 fewer may be employed, depending upon the needs of the patient. In contrast to interconnection of the cables to the rods themselves, as shown in Figure 13, cables 1402 may be applied to the screws 1406 binding the rods to the vertebrae, as shown in Figure 14.

Figures 15A and 15B illustrate yet a further, different embodiment of the invention, wherein a rigid link bar 1502 is attached to pedicle screws 1504 using nuts
15 1506 or other appropriate fasteners. With a sufficiently long exposed threaded end, multiple link members may be used in conjunction with each pedicle screw in a stacking arrangement, thereby allowing for a criss-crossed structural assembly, as shown in Figure 15B.

20 As opposed to rigid link members of a fixed length, the invention also anticipates the use of telescoping members, including the type shown generally at 1700 in Figure 17. Each end of such a device would include a flat plate, ball, or fastener such as 1702 and 1703 appropriate to one of the connector systems disclosed herein, but with the length being variable in telescoping or sliding fashion.
25 Preferably, one or more setscrews 1704 would be used to lock the member in

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accordance with a desired length at any time, including in the midst of an adjustment procedure. Any cross-sectional geometry may be used, so long as a telescoping action is provided. In particular, whereas a cylindrical geometry may allow for twisting as well as extension prior to locking in place, non-circular cross-sections may
5 be used to permit extension/contraction without twisting, as desired.

Figures 18A-18C illustrate a sublaminar connector 1800 according to the invention, having discs 1802, preferably which swivel, to which the telescoping rods of the type shown in Figure 17 may be adjustably attached. Figure 18A presents one view of such a device, showing a lower hook 1820 adapted for sublaminar
10 engagement. Figure 18B shows a top-view of the device, and Figure 18C is a cross-sectional view, with arrows used to indicate the preferred swivel action.

Figure 19 is a drawing of a further alternative device 1900 having connectors 1902, which also preferably swivel, but include a pedicle screw 1904 for fixation as opposed to a sublaminar engaging portion, as shown in Figures 18A-18C. Note that
15 although the body of the device 1900 is depicted integrally with the pedicle screw 1904, the body may be connected to lower screw portion through a connector shown with broken lines at 1910.

Installation and operation of the devices of Figures 18 and 19 are shown in Figures 20 and 21, incorporating the sublaminar device of Figure 18, pedicle screw
20 unit of Figure 19, and threaded rod of Figure 23. Figure 20 is a lateral view of an assembly utilizing these devices, whereas Figure 21 is a posterior-anterior view.

A preferred way in which the telescoping rods and fixation devices discussed above will now be described to align a problem with curvature. In Figure 22A, a telescoping rod 2202 is sized relative to a pair of connectors 2204 and 2204' to be
25 aligned, with fasteners 2206 with nuts 2208 being provided for tightening purposes.

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Figure 22B shows the telescoping rod 2202 attached to the connectors 2204, with the arrows being indicative of the way in which the segments of the rod are moved to displace the connectors prior to tightening. Figure 22C shows how the segments of the rod are locked onto the connectors in an extended position, enabling the vertebrae to be distracted and aligned. It will be clear to one of skill that, as opposed to extension, the segments of the rod 2202 may be brought together, as the case may be, to provide a desired amount of compression.

Figure 23 is a side-view drawing of a preferred cross-connector 2300 according to the invention, which may be used in conjunction, or in place of, the extensible rods just described. The assembly includes a threaded rod 2300, onto which the preferably swiveling attachment mechanisms 2304, 2304' of the connectors are journaled. On either side of the connectors, washers such as 2306, 2306' and nuts such as 2308, 2308' are also preferably used for a precise, yet stable alignment when tightening.

Although the telescoping and threaded rods have thus far been depicted as straight, they may be curved or bent for different situations. In the case of the telescoping rod, both ends may additionally be adjustable, as shown in Figure 24. The connector bodies may be attached to the rods such as 2500 in various ways, including the use of a set screw 2502 or other fastener, as shown in the cross-section of Figure 25.

Figures 26A-26C illustrate an alternative interconnection mechanism which may be used in conjunction with, or in place of, the circular swivel-type connectors described above. In this case, the connectors bodies 2602, 2602', which may feature pedicle screws or sublaminar hooks 2608, as shown, would include one or more posts such as 2620 extending therefrom, onto which elongated elements 2630 having

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closed-fork ends such as 2632, 2632' would be journaled, adjusted, then tightened for a desired level of alignment. Although a telescoping rod is shown, threaded arrangements should also be apparent to those of skill, as described above with reference to the swivel-type arrangements.

5 Figure 26A shows a telescoping version of this embodiment prior to placement onto bodies 2602, 2602'. Figure 26B shows the fork-shaped ends 2632, 2632' being placed onto the posts, and Figure 26C shows the way in which the ends are tightened onto the posts, preferably through the use of a set screw 2608 which applies pressure to the cylindrical portion of the hook to lock it into position. The
10 setscrews are locked onto the connectors to avoid the frustration of inserting the setscrew into a small space on the hook itself. Using the arrangement of the invention, the setscrews may be tightened or loosened, but will not be removed from the connector and inadvertently lost. Preferably, the cylindrical projections from the hook or pedicle screw bodies have an enlargement at their ends to help prevent the
15 connector from sliding off the hook once it is tightened in place.

 Figure 27 is a top-view drawing of an alternative connector adapted for use with any of the swivel-type embodiments described herein, the configuration permitting variable angulation in two additional planes. Figure 28 is a further adaptation of the device of Figure 28, also providing lockable angulation with
20 multiple degrees of freedom.

 Figures 29A and B will be used to introduce a series of drawings which depict an alternative connector system according to the invention. Broadly, the system uses a ball-shaped connector 2902 on a rod 2904 or other member, and wherein the spherical end 2902 fits into a socket 2906 on member 2908. Journaled over the

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element 2904 is a threaded nut 2910 which engages with threads 2912 on element 2908, thereby locking the device into a desired orientation, as shown in Figure 29B

Figure 30A is a drawing which shows an embodiment of the invention wherein a connector body and elongated element are integral, providing a low-profile solution particularly for shorter interconnections. Longitudinal member such as 3002 is incorporated into the connector to facilitate insertion into adjacent vertebrae. As such, the combined unit is inherently shorter. Also, note that the connector on the middle screw 3004 is attached to the pedicle screw through a threaded post. Once again, this shortens the unit, particularly in areas of the spine where the attachments to the vertebrae are farther apart and where more spinal deformity may be present. Multiple connectors may also be used to increase the allowed angulation between vertebrae, as shown in Figures 30B and 30C.

Figure 31A is a drawing which shows swiveling socket-type connectors on a body attached to a pedicle screw. Figure 31B shows the arrangement of Figure 31A in an assembled condition. Figure 31C is a top view illustrating the swiveling feature of the embodiments of Figures 31A and 31B. Such swivel connectors may also be incorporated into a sublaminar hook configuration. Hooks and sublaminar attachments do not require the connector-connector feature, however, since devices of this type are slid into position. Figure 32, for example, is a drawing which shows a sublaminar hook having outward projections to receive the swivel connectors.

Figure 33A is a drawing of a top view of a screw connector having two posts. Figure 33B is a top view of a screw connector according to the invention having a single post. Figure 33C is a top view of a hook connector. Figure 33D is an oblique drawing which shows a preferred use of frictional surfaces to lock in the swivel action upon achieving a desired orientation. The friction surface may also be incorporated

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between the connectors and the screws or hooks. Figure 33E shows how a set screw (or screws) may be added to help control rotation of a connector according to the invention.

The combined longitudinal member-connector unit may feature a variety of
5 lengths for the longitudinal members, as well as angles between the longitudinal member and connector. Figure 34A, for example, shows how a combined longitudinal member and connector may have a particular length and angle to address a particular situation. Figure 34B illustrates an assembled version of the angled unit of Figure 34A.

10 Figure 35 is a series of drawings which show a variety of longitudinal members in straight and curved configurations. The longitudinal members shown in Figure 35 are preferably pre-fabricated in various sizes and shapes with the nuts attached. They are used when the space between the attachment sites on the vertebrae are close together. Depending upon material choice, they may be further bent by the
15 surgeon at the time of surgery as necessary. When the space between the vertebrae attachment sites is larger than the telescoping longitudinal member, a turnbuckle-like longitudinal member would preferably be used. It will be appreciated that these and other ball-ended configuration may incorporate the cap configurations of Figures 3G.

The telescoping/turnbuckle members with nuts could also be assembled by the
20 surgeon. For example, Figure 36A shows how a telescoping member may be assembled through a pair of nuts then joined. Figure 36B shows a joined assembled version of the assembly of Figure 36A.

The cross links may also be attached to the top of the central posts in many different configurations. Figure 37 illustrates one embodiment of the cross-link which
25 are plate-like. This embodiment shows only one cross-link end per connector.

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Alternatively, for more rigidity, the cross links could be stacked. Figure 38 shows an embodiment with two cross-link ends/connector. The longitudinal members are connectors were not drawn to show cross-links better. The cross links illustrated in Figure 38 are preferably thinner than the rigid longitudinal members in Figures 14 and 15. Figure 39 is a side view of a connector including a cross link;

This section of the description provides details of various connector configurations according to the invention, including designs particularly suited to different vertebral levels. In the accompanying drawings, the central connector bodies are threaded at the ends where engage with the longitudinal members. As discussed elsewhere herein, the central connectors may be threaded on either end, though the connectors at the end of a construct are preferably threaded on one end only. The central portion of the connector may include a flat surface, or may be square or rectangular to accommodate a wrench to stabilize the connector while tightening the nut and facilitate attachment to pedicle screw. The central portion of the connector may further include a pedicle hole to attach the connector to a pedicle screw. A friction surface may be provided between the connector (interior surface) and the pedicle screw superior surface.

Figures 40A-40F provide different views of a central lumbar connector according to the invention. In the lumbar region in particular, the connectors should be as short as possible. The pedicle screws may be 3 cm apart or closer. In this and in other embodiments, a friction surface may be provided between the rod ends and the connector seat. The connectors should be as small as possible in every dimension, since prominent hardware could cause the patient to experience pain.

Figures 41A-41G depict different views of a connector adapted to the cephalad end. As shown in Figures 41B and 41G, in particular, such connectors may

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have a special shape to avoid impingement on the first mobile facet joint of the spine. This is perhaps better visualized in Figures 58A and 58B. Note that if the inferior surface has a friction surface left and right units may be provided. Without a friction surface, however, the connector may be turned over for the other side. A special
5 wrench (not shown) may also be provided to hold the connector while tightening the nut. The wrench could be the female version of the non-threaded portion of the connector attached to a handle.

The caudal end may use same connector as used in cephalad end. A reduced profile is not necessary, and the connector is similar in every other way to the
10 cephalad connector. These connectors may also be used in other positions in patients with spinal deformities. Two connectors will preferably be used per pedicle screw or hook. The portion of the connector that attaches the hook or screw should be as small as possible to allow the connector to rotate. The connector should be as strong as possible to prevent fatigue fracture. If the connector is strong enough, it could also be
15 used in the lumbar spine rather than the end connectors described above. This arrangement could reduce manufacturing costs by using a single type of end connector.

Figures 42A-42E show different views of a thoracic connector according to the invention. Figures 43A and 43B show an exploded and assembled views of
20 sublaminae hooks with thoracic connectors attached thereto. Figures 44A-44C are top views showing swiveling before and after locking into a straightened configuration. The connectors rotate until tightening to allow for spinal deformity. They can be loosened and retightened to provide a desired level of correction.

Figure 45 is a drawing of a pedicle screw used to discuss different sizes and
25 diameters according to the invention. In the preferred embodiments, the pedicle

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screws feature a tapered minor diameter. Most screws break at the connection to the rod, since the bone near the tip of the screw is cancellous, whereas bone near the connector end is cortical. The deeper thread near the tip and constant major diameter for most of the screw serves to enhance pull-out strength. However, a relatively blunt
5 tips are preferred to avoid vascular injury if the screw tip extends through the vertebra. Generally a tap is used to provide a pathway for the screw. The bone is soft and some surgeons avoid the tapping step. Often a surgeon uses a tap for a 5.5 mm screw but insets a 6.5 mm screw.

Figure 46 is a perspective view of the pedicle screw of Figure 45 including a
10 ball connector and link bar. Figure 47 is a drawing of the configuration of Figure 46 in an assembled state. Figure 48 is an assembled connector having two opposing ball-receiving sockets. Note that pedicle screws for independent double connectors may require a different (i.e., longer) design. Figure 49 is a drawing of an exploded and assembled view of a pedicle screw having independent double connectors. Figure 50
15 shows how a non-round interconnection may be used to prevent rotation of the pedicle screw relative to a connector body.

This invention also provides 'open' pedicle screws which may be deployed when there is not enough room at 5100 between screws to allow connectors, as shown in Figure 51. Figure 52A shows such a hinged connector in an open condition,
20 whereas Figure 52B shows the hinged connector locked onto a rod. Indeed, it will be appreciated that most, if not all, of the various embodiments described herein may, at least in some way, be adapted for use with spinal rods of the type now in common use.

Figures 53A-53M illustrate the alternative use of straps according to the
25 invention for rod movement and stabilization. Figure 53A depicts a pedicle screw

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5300 having lower threads 5304 and body 5302 with rod-receiving area 5306 and threads 5308 for a compression fastener (not shown). An indentation 5310 is provided on the side for grasping. Typically, surgeons force spinal rods into such pedicle screws and vertebral hooks with bulky clamps and threaded "rod pushers" as depicted schematically in Figure 53B. This presents significant disadvantages. For one, the clamps and rod pushers are bulky. The large clamps and pushers also frequently impinge on one another. To avoid impingement, surgeons often place excessive force on a single screw or hook to allow placement of a setscrew to hold to hold the rod in place, enabling the surgeon to remove the clamp. The excessive force on a hook or screw can crack the vertebra, and the bulky clamps may interfere with setscrew placement.

The embodiment of Figures 53D through 53M uses wires, cables, or straps to force spinal rods into pedicle screws and hooks. The preferred embodiment uses plastic straps cable ties (5344) as tightening tools. The straps may be removed (Figure 53L) once the rod is held in place using setscrews or nuts. Figure 53D shows the use of a strap piece 5340 for such purpose. As shown in Figures 53E and 53F, the strap piece 5340 is preferably rotatable beneath the both of the rod fastener.

Figure 53G shows a cable tie 5344 engaged with the strap piece 5340 prior to tightening. Figure 53H shows the cable tie tightened and the rod in place within the pedicle screw. Figure 53I shows the alternative use of a removable strap piece 5350. Figure 53J shows a cable tie 5344 engaged with the strap piece 5350 prior to tightening. Figure 53K shows the cable tie tightened and the rod in place within the pedicle screw. Figure 53M shows how this and other aspects of the invention are not limited to pedicle screws, but may also be configured for sublaminar hooks and other devices.

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The use of cable ties and straps has several advantages. The straps are less bulky than the clamps and pushers currently in use. Straps, with locking mechanisms, hold tension after the tightening tool is removed. As such, the tightening tool can be removed from the wound, giving the surgeon more room to work. Straps can be tightened repeatedly as the rod advances into several hooks or screws. Thus, the loads are shared by multiple spinal attachment sites rather than a single attachment site. Vertebral fracture is therefore less likely. The straps, cables, and wires are lateral to the hook and screw rod connection. Accordingly, the lateral position does not interfere with setscrew placement.

The elongated members or rods according to the invention may also be provided in a variety of configurations, including solid-, non-telescoping, telescoping, turnbuckle, and different lengths and shapes. The solid rods with spherical ends may be manufactured with the nuts in position, or half washers may be used as shown in Figures 56 and 57 to reduce costs. Rods with single spherical end rods may use nuts added by the surgeon in lengths which may be cut at the time of surgery to customize.

Figure 54 is a side view of a turnbuckle rod according to the invention. Preferably, such a device exhibits a contracted length on the order of 3 cm while being expandable to 10 cm or beyond. Many different sizes may be provided as necessary to accommodate a greater range. Figure 55 is a drawing which shows the combined use of ball-and-socket connectors in conjunction with optional criss-cross link bars. Such bars are preferably narrow, on the order of 2 mm thick, in 2 cm - 10 cm lengths with 3 mm increments.

As discussed above, the nuts may be added to solid rods after the rods are manufactured using half- or slotted washers. Figure 56 shows how a half-washer may be used in conjunction with a nut opening that is large enough to slide over the

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sphere at the end of a rod. Figure 57 shows an alternative use of a slotted washer permitting a nut to slide over the spherical end of a solid rod.

Prior-art spinal rods, screws, and plates risk impingement on the first mobile facet cephalad to the fusion. For example, the inferior facet of L₄ may impinge on the plate, rod, nut, or connector extending from L₅ to S₁ in a L₅-S₁ fusion. Impingement can lead to pain, facet arthritis, facet fracture, and additional surgery. What is needed is a reduced profile connector to prevent impingement. Figure 58A is a drawing which shows a modified connector adapted to reduce impingement. Figure 58B is a drawing of an anti-impingement connector utilizing a ball-and-socket arrangement.

Figures 59A and 59B are different views of a transverse connector according to the invention. The transverse connector (cross brace) fits on the rods between the hooks. Figure 60 shows the combined use of transverse connectors and hinged hooks which lock onto a solid rod. The convex solid rod may be placed after the modular system to restore the spine to its proper alignment. The convex rod may include an octagonal or other cross-section to prevent rotation of cross brace on the rod, as shown in Figure 61. For example, the convex rod may have longitudinal grooves. Such features may travel the length of the rod or be interrupted. Figure 62A illustrates the use of a continuous shaped rod, in this case having a grooved cross-section. Figure 62B illustrates how the modification along the rod may be interrupted along its length.

Figure 63 is a drawing which shows a bevel connector embodiment according to the invention. Such a connector allows 15-20 (or more) degrees of angulation before tightening. Although this type of connector is used in current spine implants, prior art configurations use only one rod on each side of spine. This embodiment of the invention allows use of multiple rods/side as shown in Figure 64. Indeed, it is

believed that the modular hooks and screws according to the invention represent the only system that allows two rods to be attached to a single rod hook or screw.

Figure 65A is a drawing which shows a stabilization clamp for use with various embodiments disclosed herein. Figure 65B is an end of the configuration of
5 Figure 65A. Figure 66A is a different alternative embodiment of a stabilizing assembly, and Figure 66B is a cross-section of the assembly of Figure 66A.

Figures 67A-67C illustrate the use of lockable swivel-type connectors 6704, 6704', which may be fastened to one or, preferably a pair, of parallel (or non-parallel) rods 6702, 6702' to provide a desired degree of alignment and correction. This
10 particular embodiment uses a modified hook structure and setscrew arrangement, which may be moved along the rod, as shown in Figure 67B, until a desired degree of separation/ orientation is achieved, at which point all of the various components may be tightened into place with fasteners 6710, 6710'.

To ensure stable interconnections that do not loosen through movement or
15 degrade with time, the invention may take advantage of materials and/or geometries to enhance structural integrity. For example, shape-memory technology may be used to assist in locking the screws, rods, caps, joints and other components to one another. Such interfaces may be mobile until body temperature changes the dimensions to promote a tighter fit, where applicable. In addition, particularly with respect to
20 threaded fasteners, the thread sizes may be slightly mismatched to promote a slight galling for an even tighter fit.

I claim:

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1. A spinal alignment system, comprising:
 - 2 a rigid elongated element terminating in a shaped end;
 - a connector body having a lower portion configured for spinal engagement,
 - 4 and an upper portion configured to receive the shaped end such that the elongated element is temporarily angularly movable relative to the connector body; and
 - 6 a fastener for locking the shaped end into position once a desired angular relationship is established between the rigid element and the connector body.
2. The spinal alignment system of claim 1, wherein the lower portion
 - 2 configured for spinal engagement is a pedicle screw.
3. The spinal alignment system of claim 1, wherein the lower portion
 - 2 configured for spinal engagement is a sublaminar hook.
4. The spinal alignment system of claim 1, wherein the elongated element
 - 2 has two ends, each terminating in a shaped end to be received by a connector body.
5. The spinal alignment system of claim 1, wherein:
 - 2 the shaped end is at least partially spherical; and
 - the upper portion includes a cup-shaped socket to receive the spherical end,
 - 4 and a side opening through which the elongated element extends.
6. The spinal alignment system of claim 5, wherein the elongated element
 - 2 has two spherical ends, each to be received by a different one of the connector bodies.

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7. The spinal alignment system of claim 6, including a plurality of
2 elongated elements with ends that terminate in half spheres, enabling the ends of such
elements to be mated to form a single spherical joint.

8. The spinal alignment system of claim 7, wherein the upper portion of
2 the connector body includes a cup-shaped socket to receive the spherical joint, and
opposing side openings through which each of the mated elongated elements extend.

9. The spinal alignment system of claim 8, wherein the mated elongated
2 elements may be angled relative to one another while maintaining the spherical joint,
such that the fastener may be used to lock the spherical joint into position to achieve a
4 desired angular relationship between each element and the connector body.

10. The spinal alignment system of claim 7, further including half
2 spherical caps that fit over the ends of the elongated elements that terminate in half
spheres, thereby forming a ball-shaped end to be received by the upper portion of the
4 connector body.

11. The spinal alignment system of claim 7, wherein:
2 the half spherical ends of the elongated elements include a flat surface; and
the elements mate by positioning one flat surface against another.

12. The spinal alignment system of claim 11, including an elongated
2 element that defines an axis, and the flat surface is not perpendicular to the axis.

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13. The spinal alignment system of claim 7, further including a feature to
2 maintain the spherical shape of the joint as the elements with the half spherical ends
are angled relative to one another.

14. The spinal alignment system of claim 1, further including an elongated
2 element having a length-adjustment mechanism.

15. The spinal alignment system of claim 14, wherein the length-
2 adjustment mechanism includes a telescoping portion and locking fastener.

16. The spinal alignment system of claim 14, wherein the length-
2 adjustment mechanism includes a turnbuckle.

17. The spinal alignment system of claim 1, wherein the upper portion of
2 the connector body includes a top opening to receive the shaped end and fastener, and
a side opening in communication with the top opening through which the elongated
4 element extends.

18. The spinal alignment system of claim 17, wherein:
2 the fastener is a threaded compression fastener; and
a tension band configured for positioning around the upper portion of the
4 connector body when the shaped end is compressed by the fastener to minimize
spreading of the top opening.

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19. The spinal alignment system of claim 1, wherein the upper portion of
2 the connector body includes a top opening to receive the shaped end and opposing
side openings in communication with the top opening.

20. The spinal alignment system of claim 19, wherein the top opening is
2 also capable of receiving an alignment rod without a shaped end when extending from
both of the side openings when locked into position by the fastener.

21. The spinal alignment system of claim 20, further including a strap
2 engagement feature associated with the connector body, enabling a cable tie to be
placed around the engagement feature and alignment rod and tightened to pull the rod
4 into the top opening of the upper portion.

22. The spinal alignment system of claim 1, wherein the upper portion is
2 configured to receive the shaped ends of two elongated elements such that each
element lockingly extends from opposing sides of the connector body.

23. The spinal alignment system of claim 22, further including a
2 mechanism that clamps onto both of the elongated elements at points away from the
connector body for added structural stability.

24. The spinal alignment system of claim 1, further including:
2 a separate connector body having a first portion configured for locking
engagement to an alignment rod without a shaped end, and a second portion

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- 4 configured to receive the shaped end such that the elongated element is temporarily
angularly movable relative to the separate connector body; and
- 6 a fastener for locking the shaped end into position once a desired angular
relationship is established between the rigid element and the separate connector body.

25. The spinal alignment system of claim 1, wherein the cross section of
2 the alignment rod is a circle or regular polygon.

26. The spinal alignment system of claim 1, wherein the cross section of
2 the alignment rod is hexagonal.

27. The spinal alignment system of claim 24, wherein first portion is also
2 configured for locking engagement to one of the elongated elements having a shaped
end.

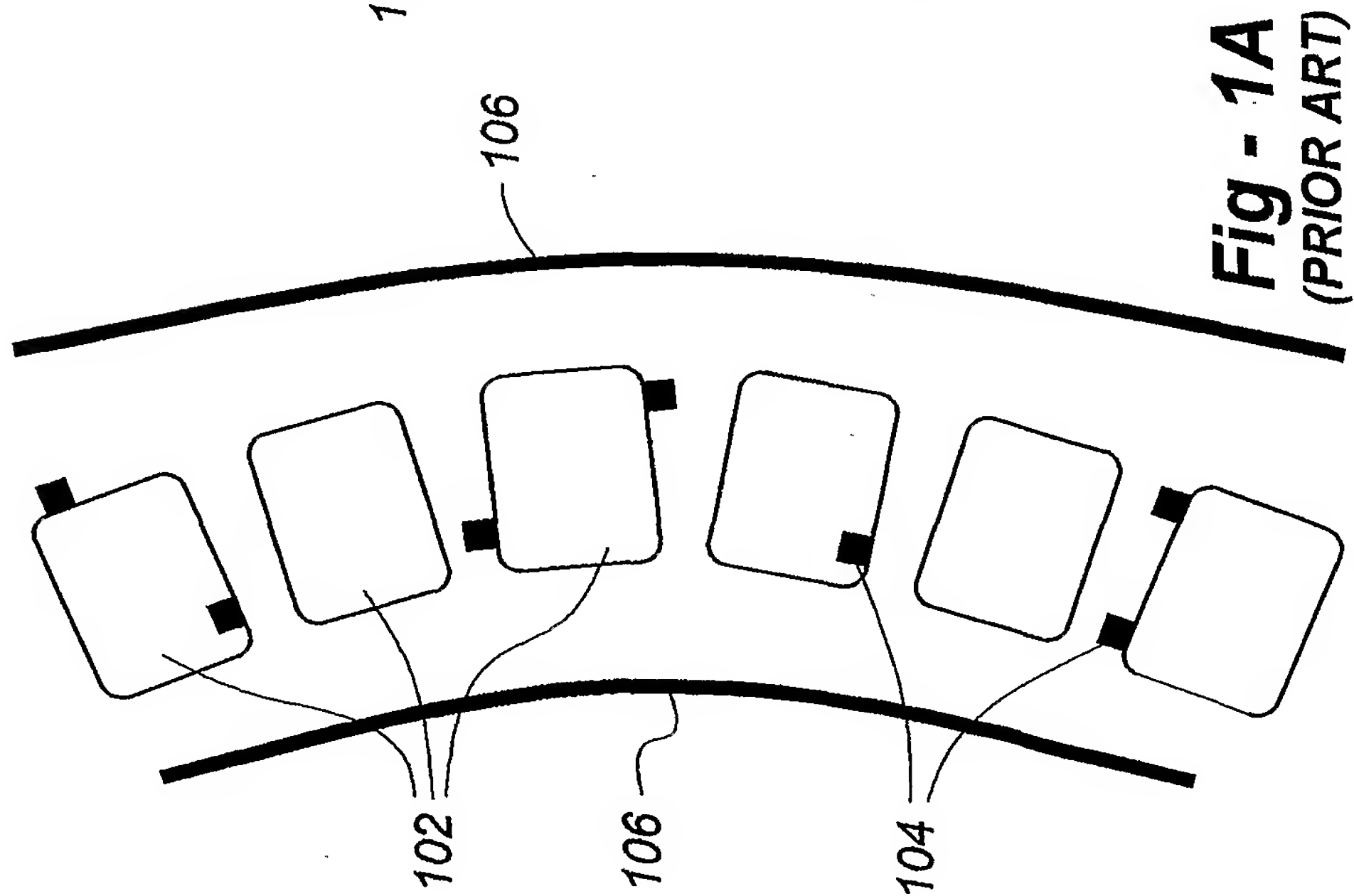
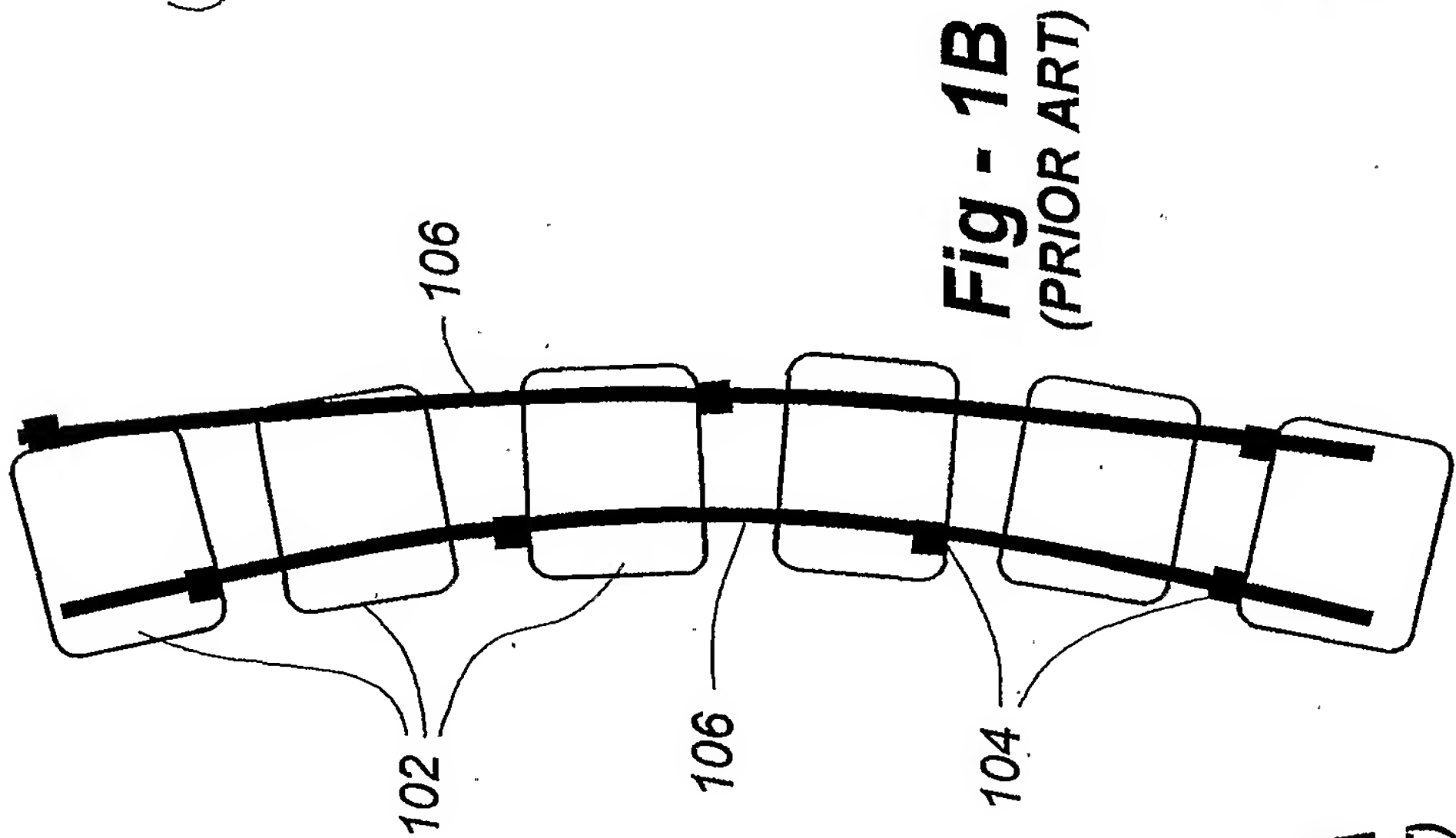
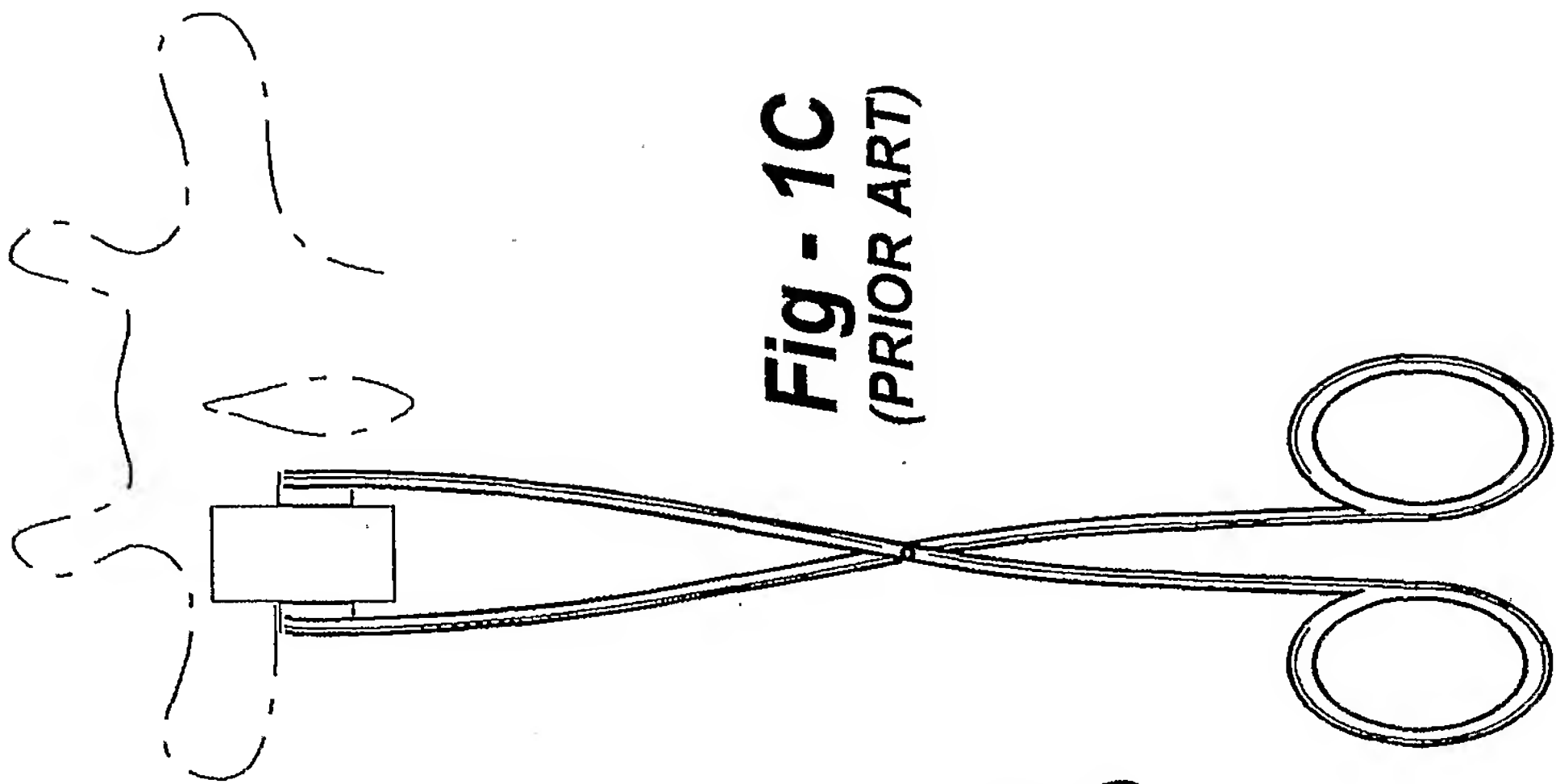
28. The spinal alignment system of claim 24, including an elongated
2 member having opposing shaped ends, enabling the separate connector bodies to be
locked onto alignment rods and used for cross-bracing.

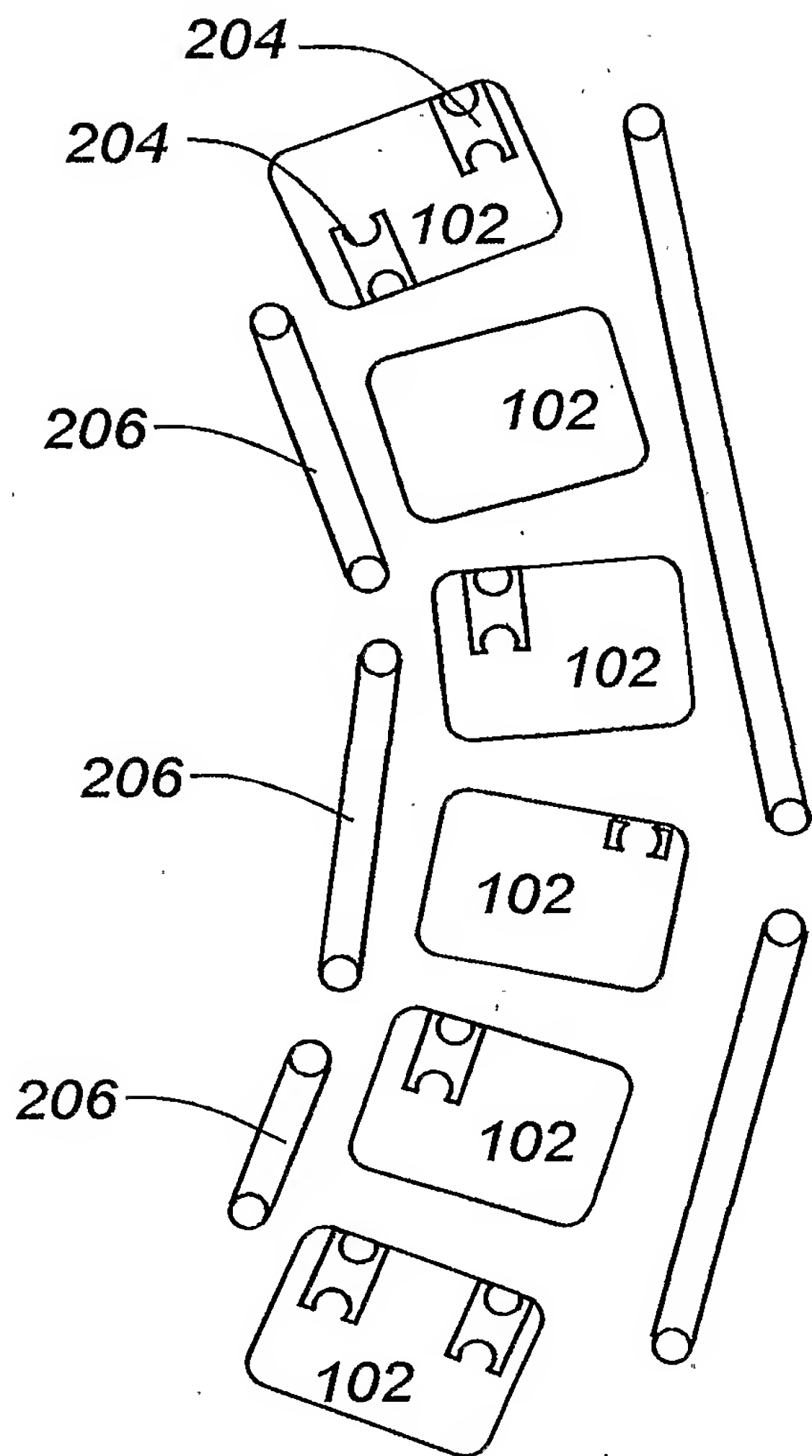
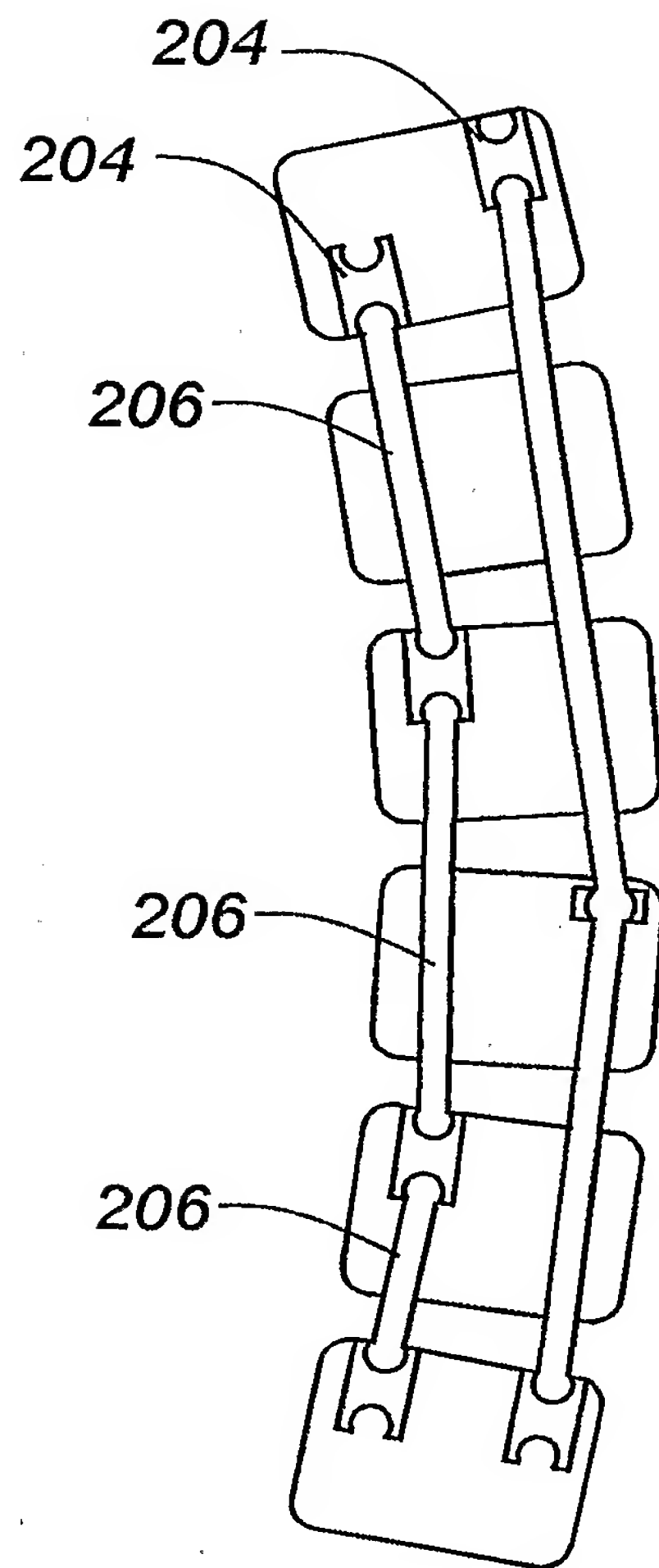
29. The spinal alignment system of claim 1, wherein the shaped end is a
2 flat disk.

30. The spinal alignment system of claim 29, wherein the flat disks may be
2 stacked onto one another such that multiple elongated elements extend from the
connector body.

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31. The spinal alignment system of claim 1, wherein:
- 2 the upper portion includes a post;
- the shaped end of the elongated element includes a hook having opposing tines
- 4 that straddle the post; and
- the fastener squeezes the tines together to lock the element into position.



**Fig - 2A****Fig - 2B**

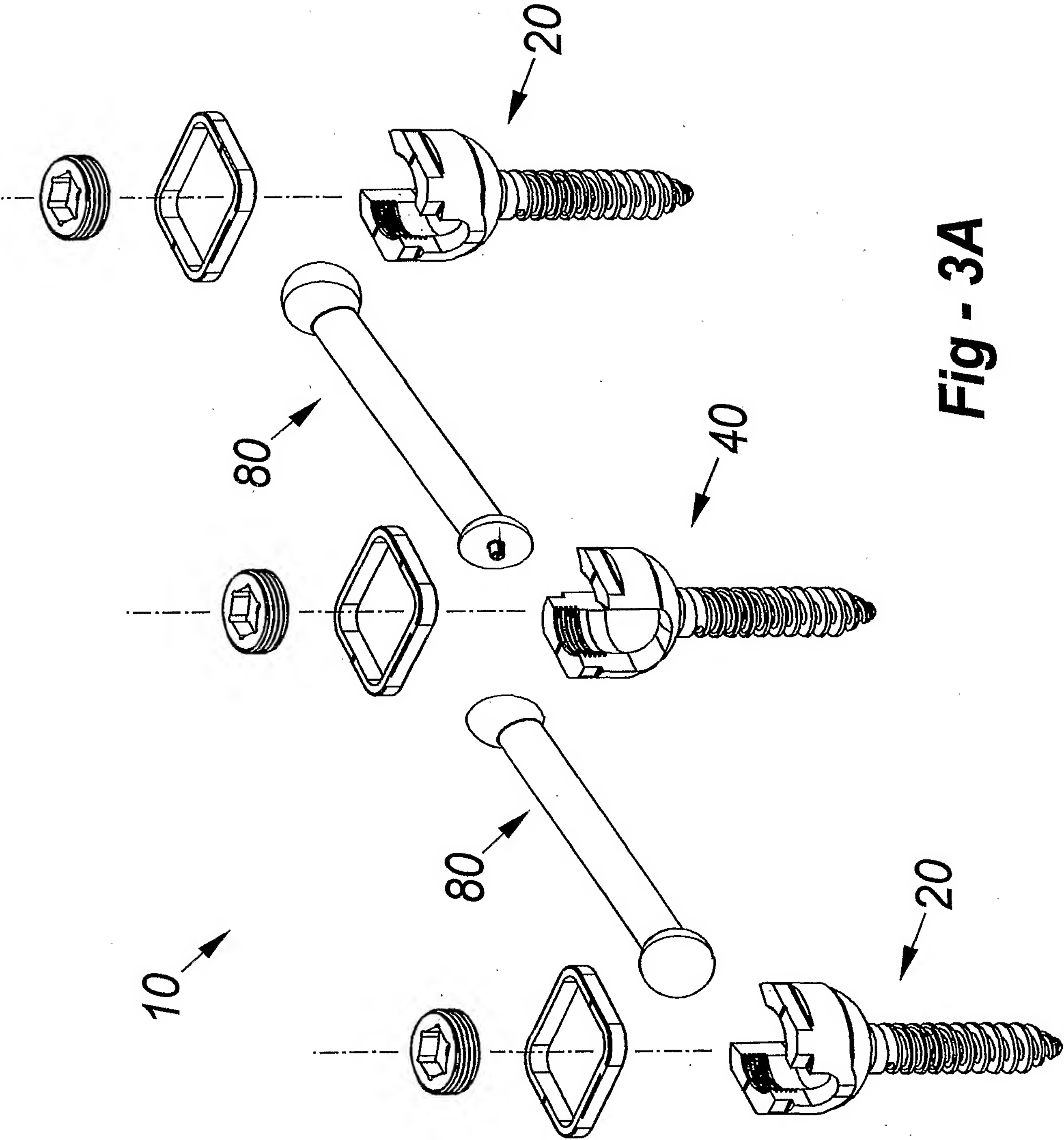


Fig - 3A

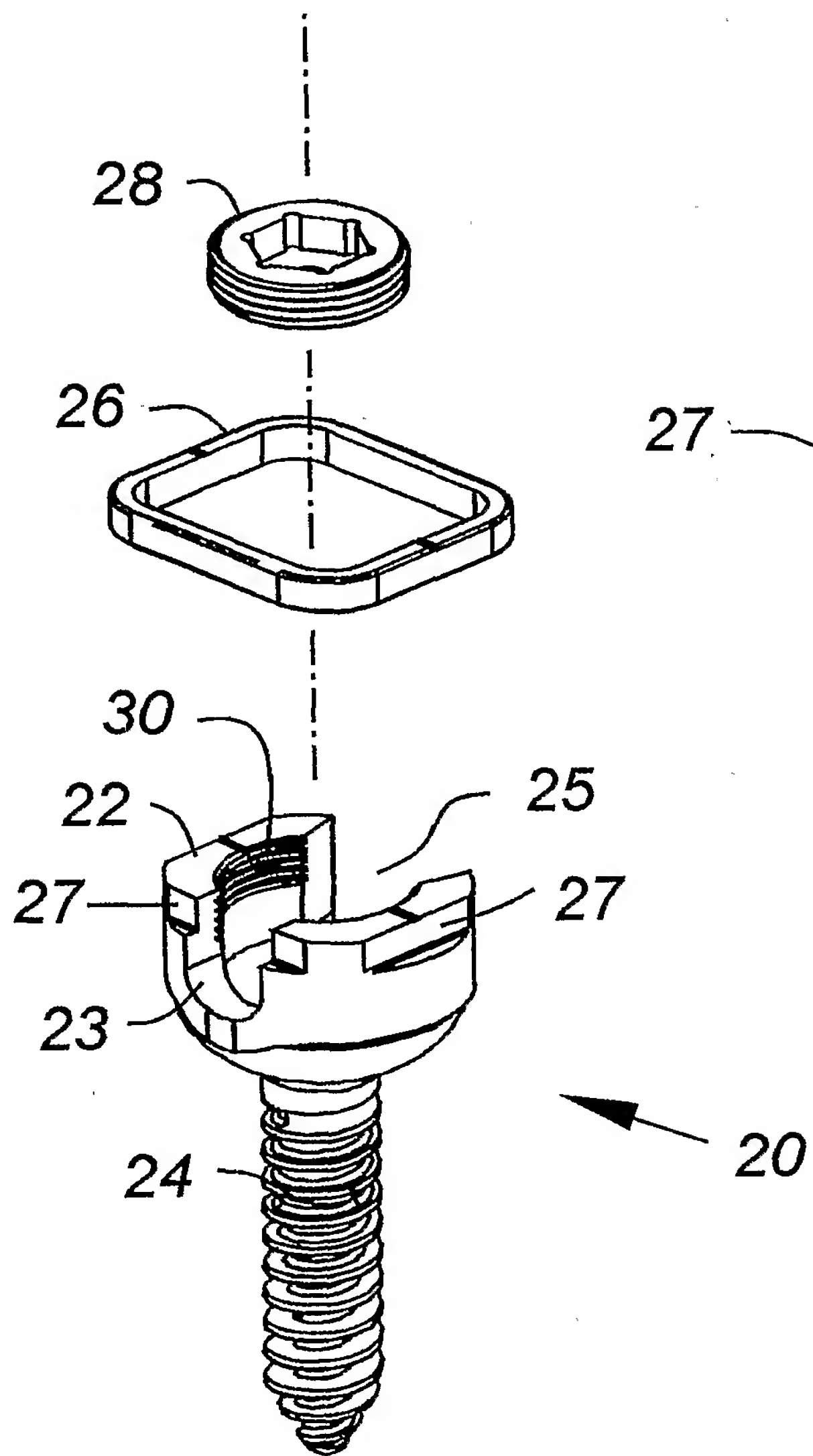


Fig - 3B

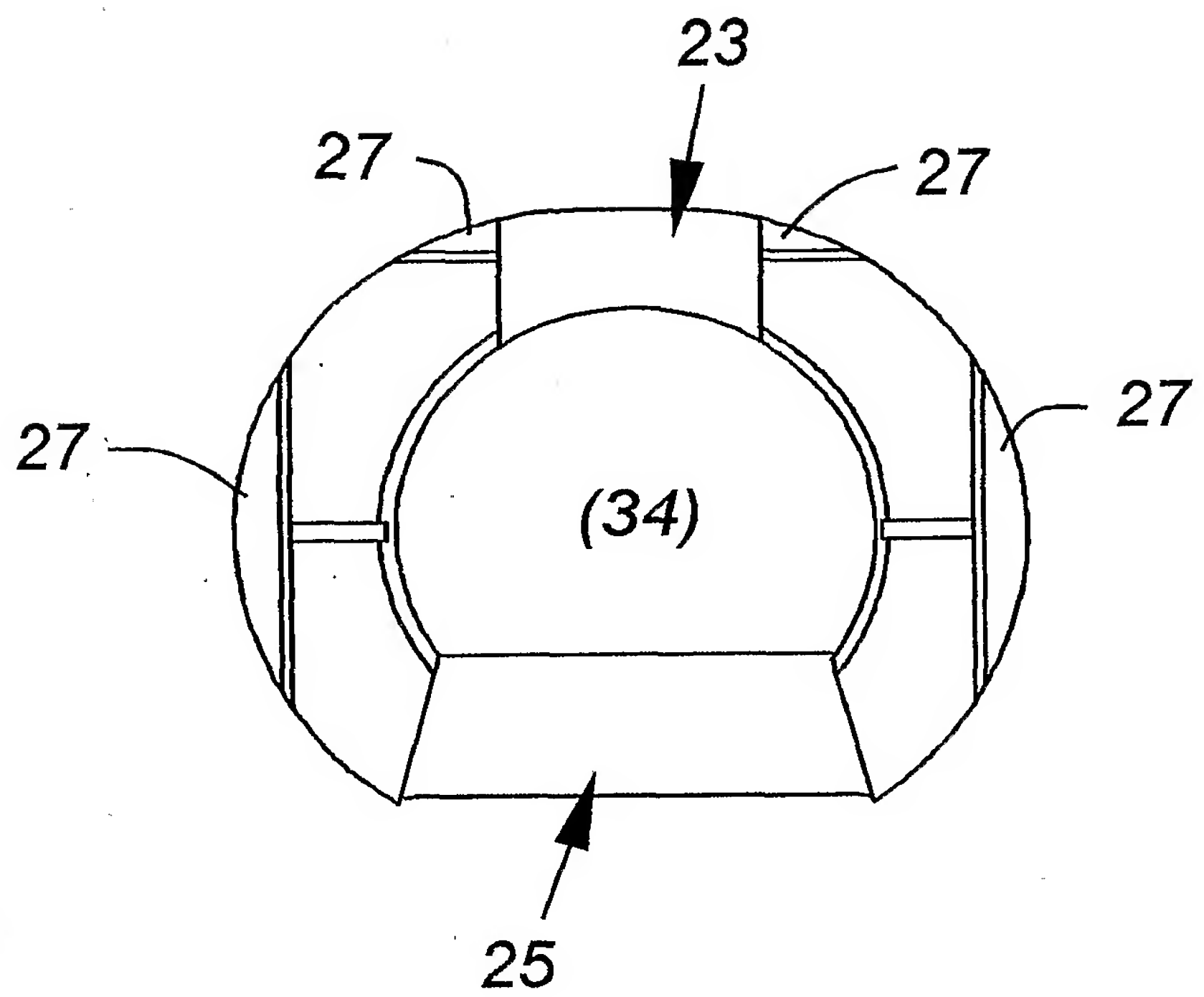


Fig - 3C

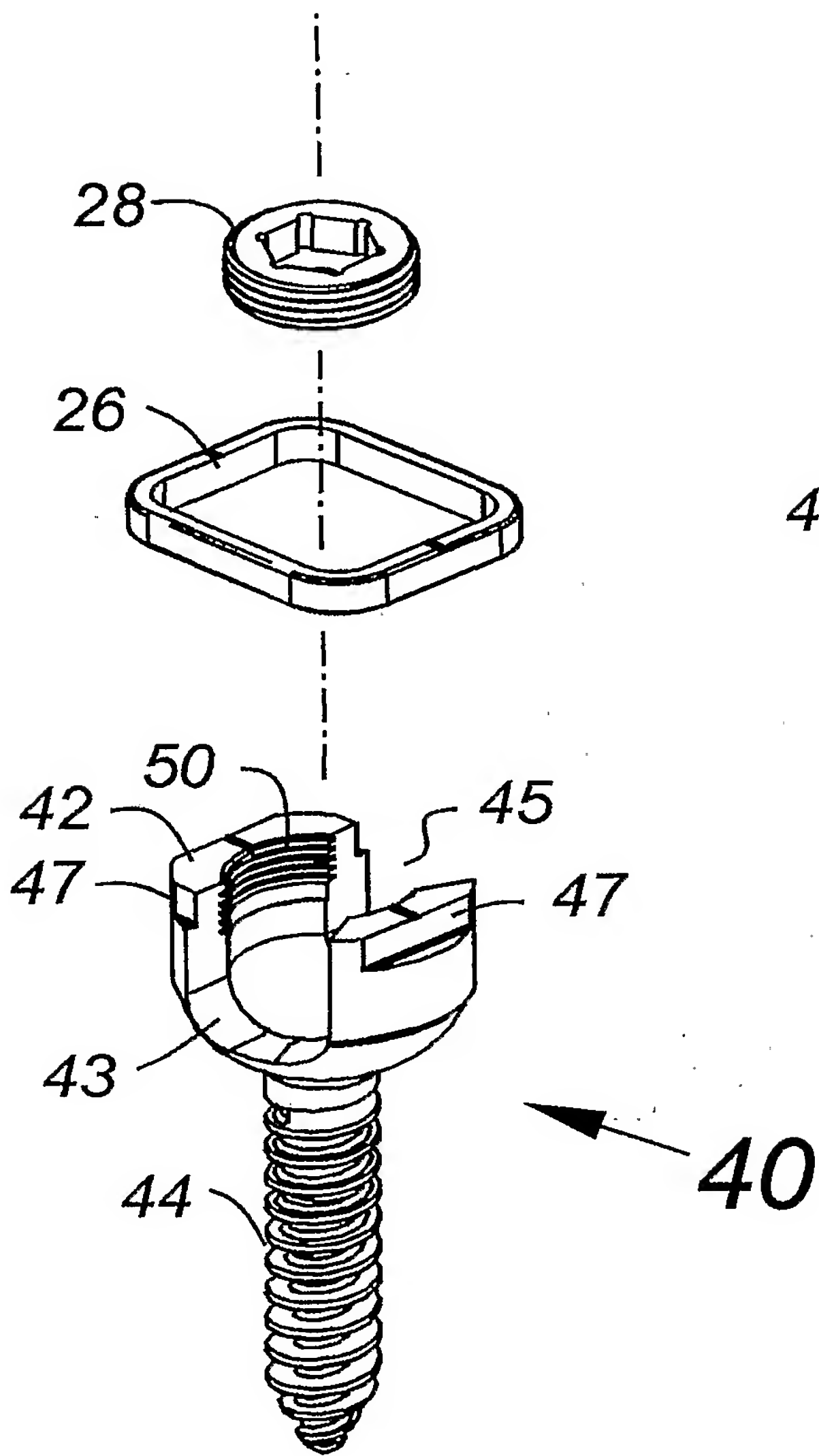


Fig - 3D

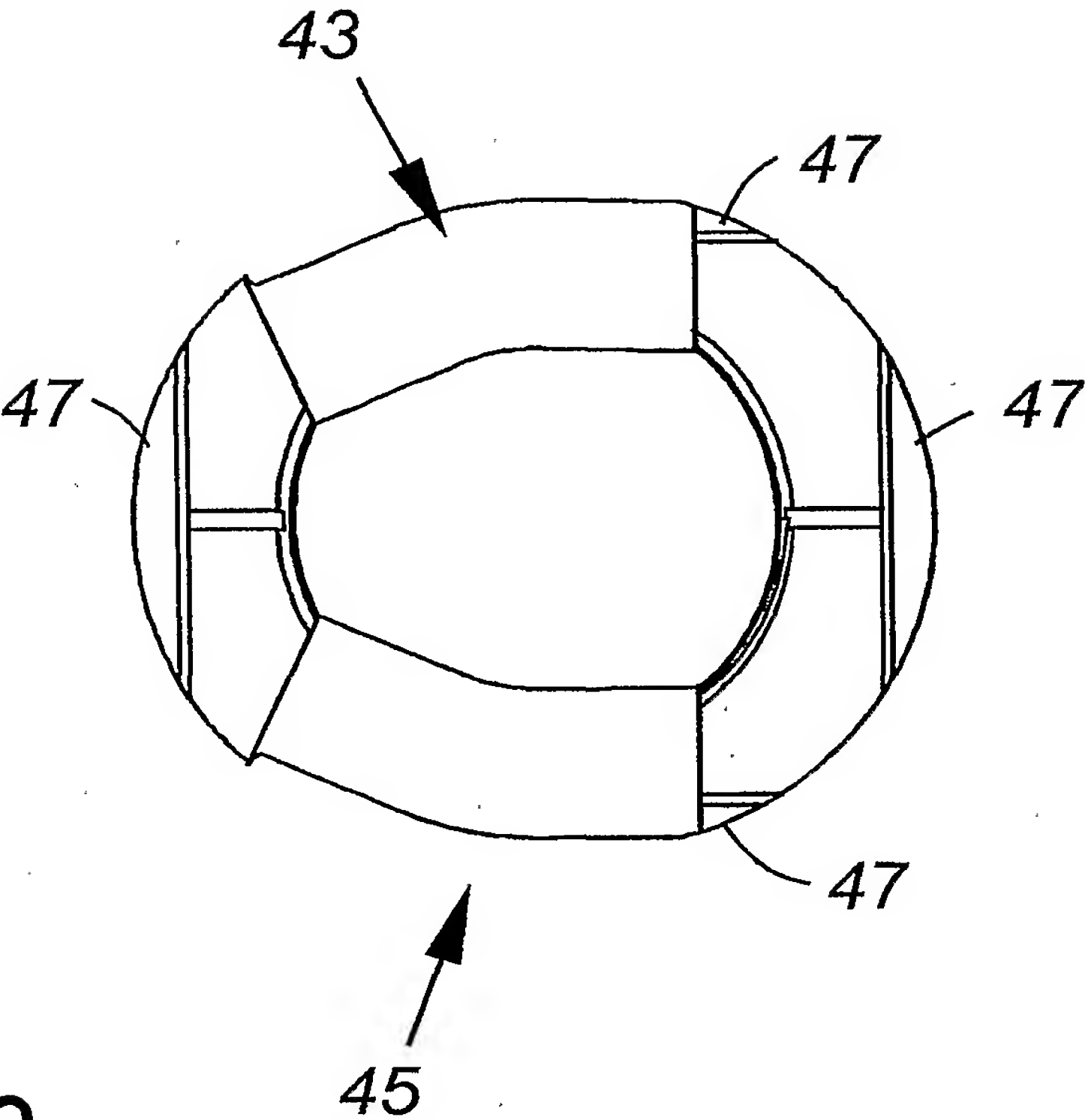
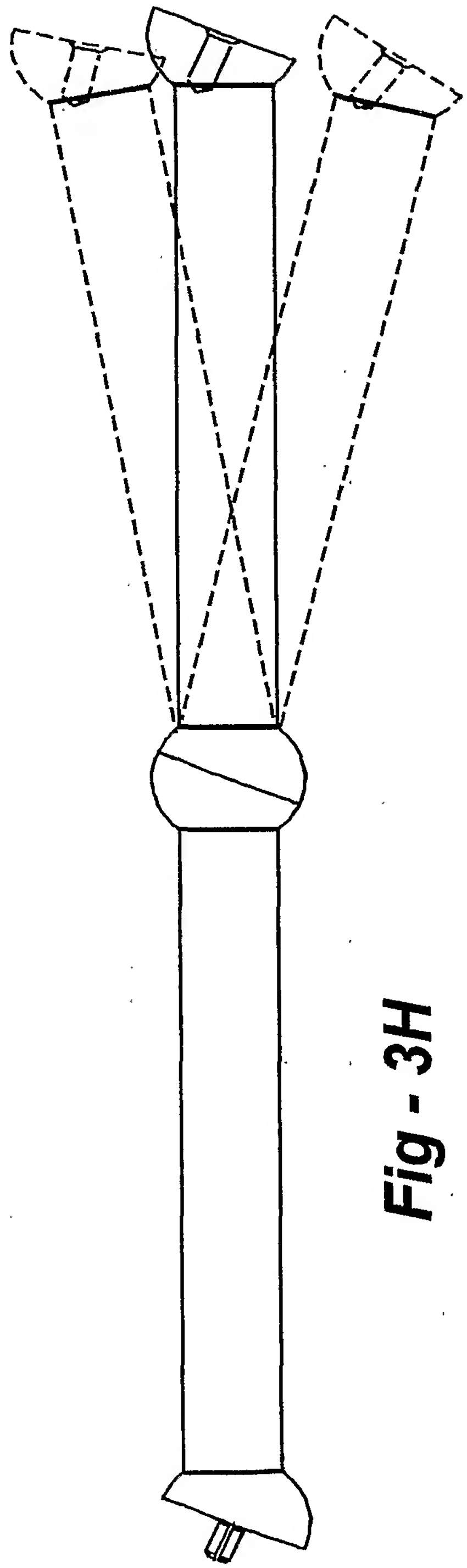
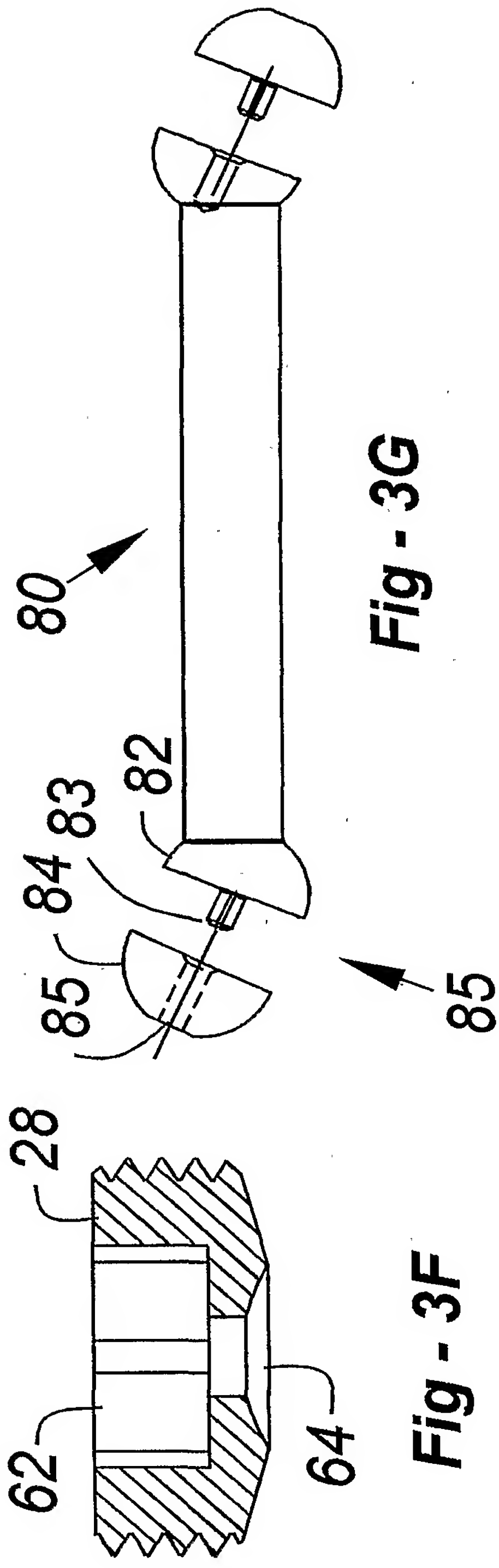
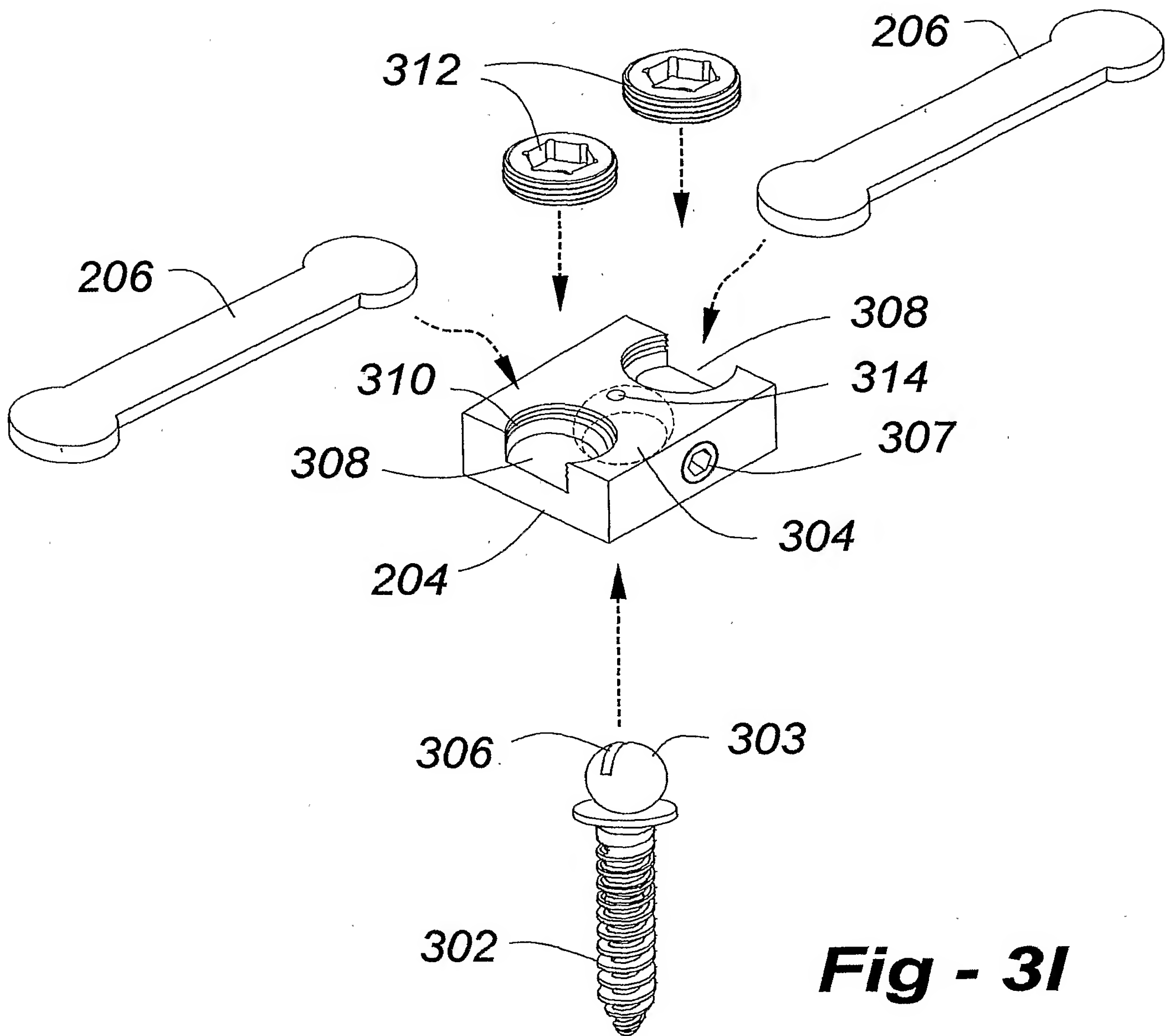
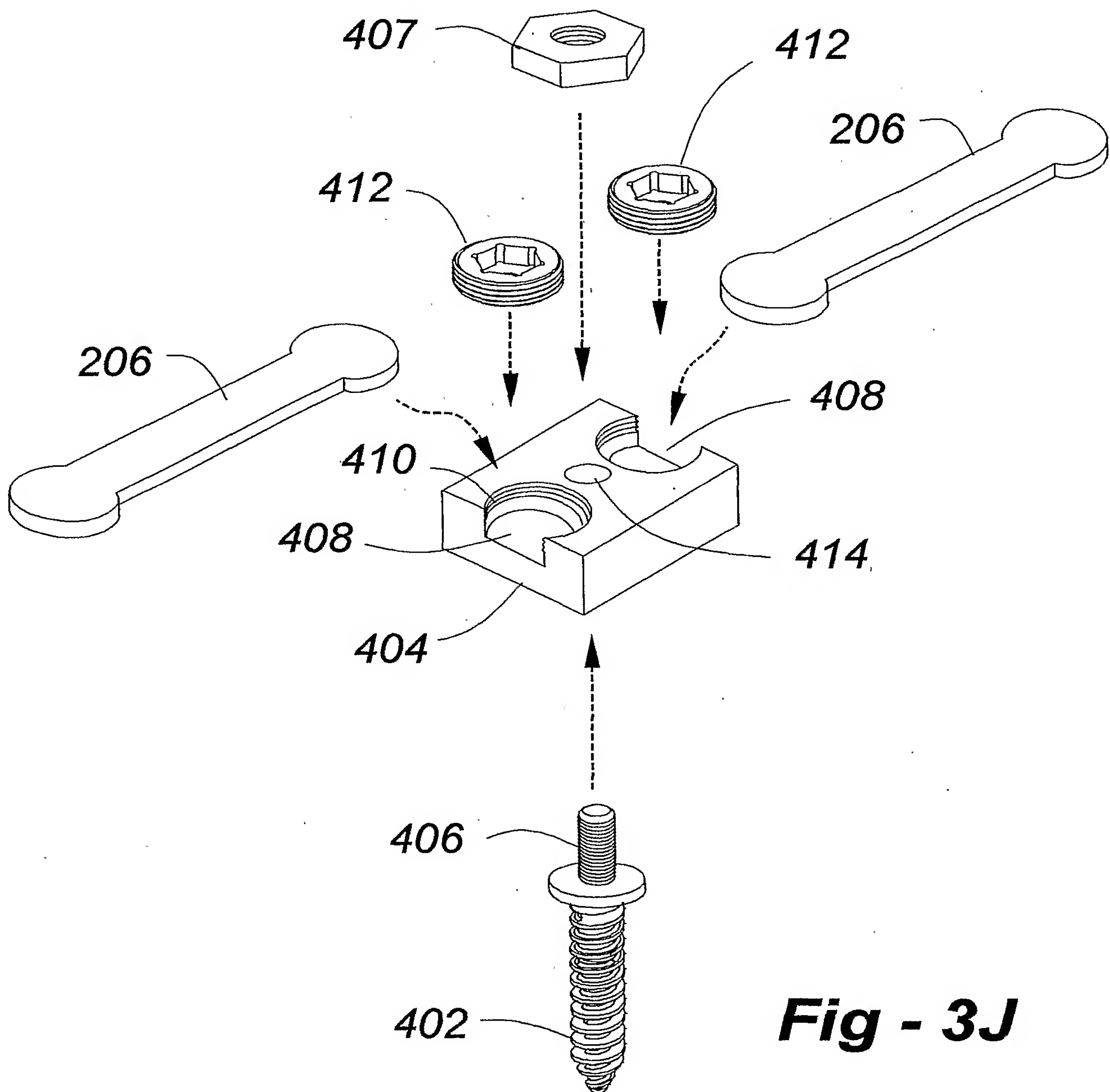


Fig - 3E







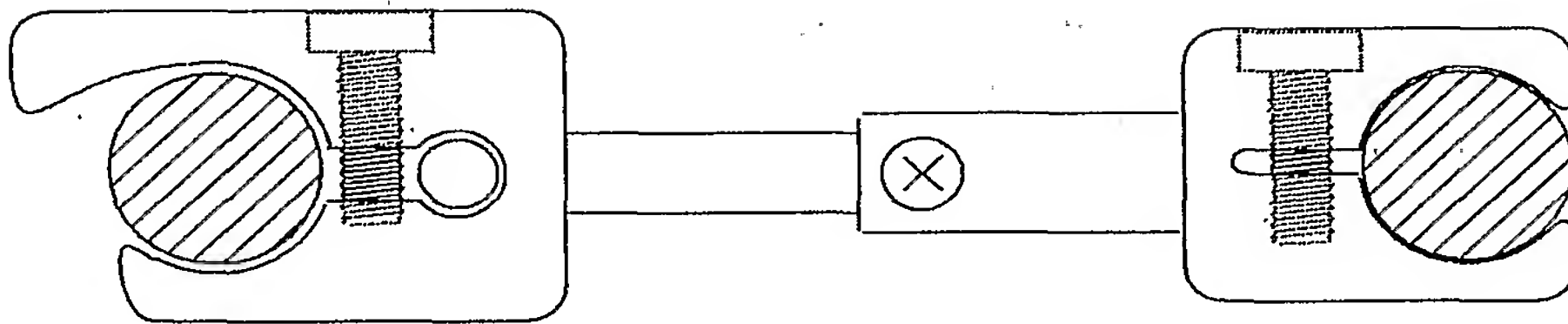


Fig - 3K

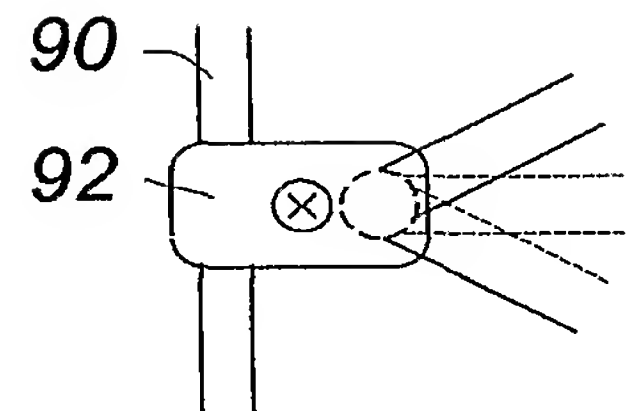


Fig - 3M

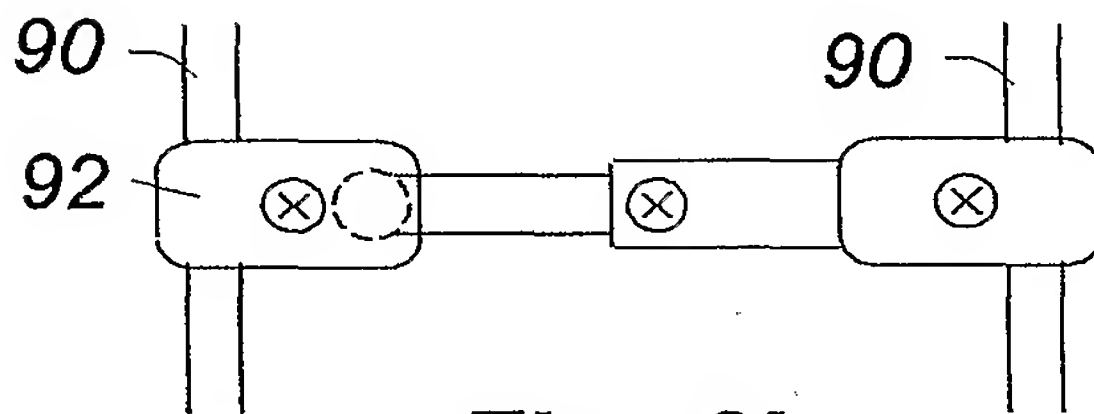


Fig - 3L

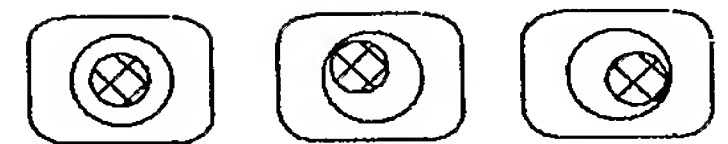


Fig - 3N

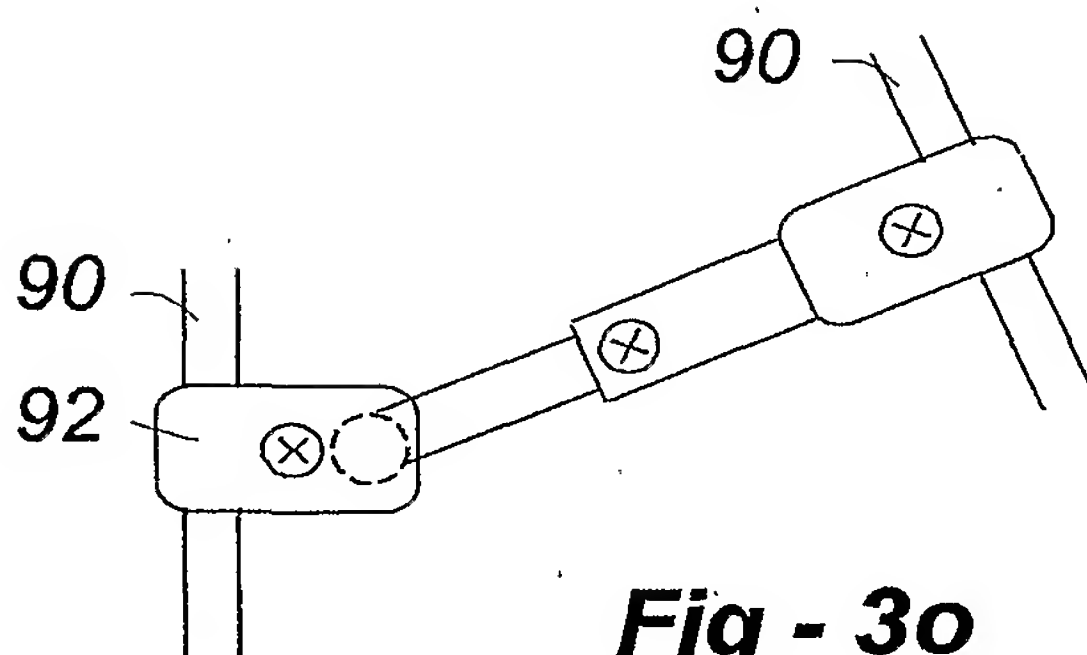


Fig - 3O

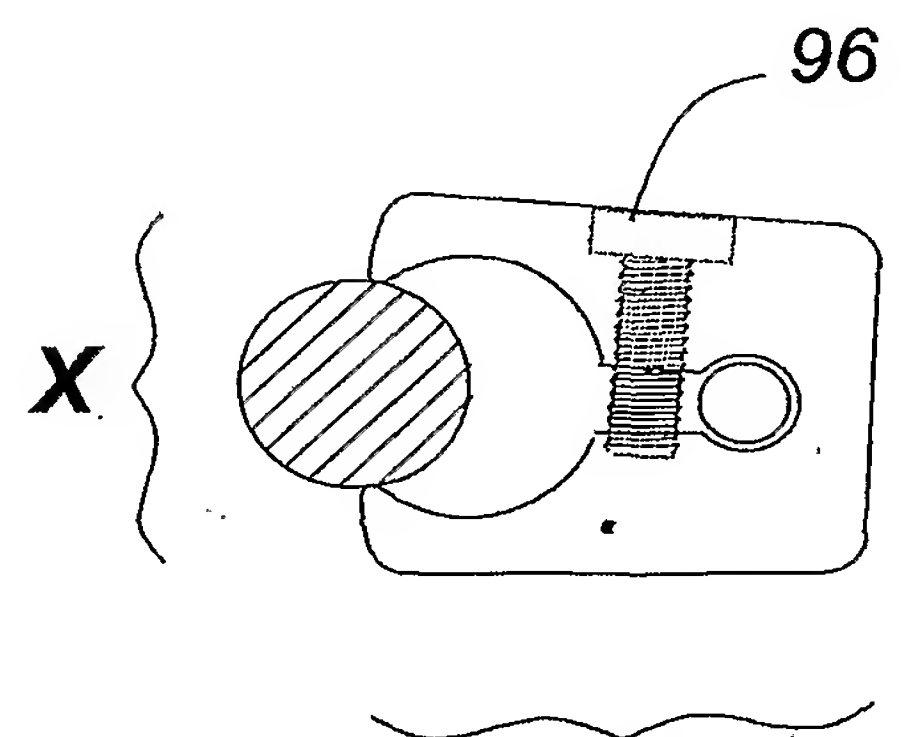


Fig - 3P

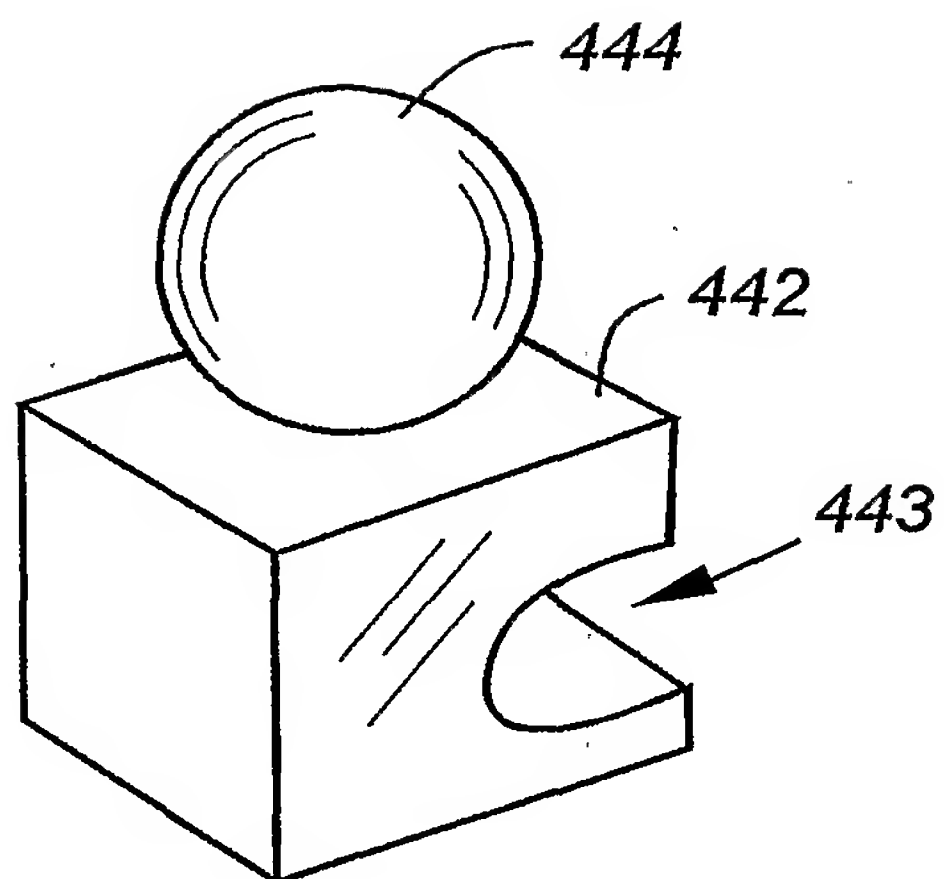


Fig - 4A

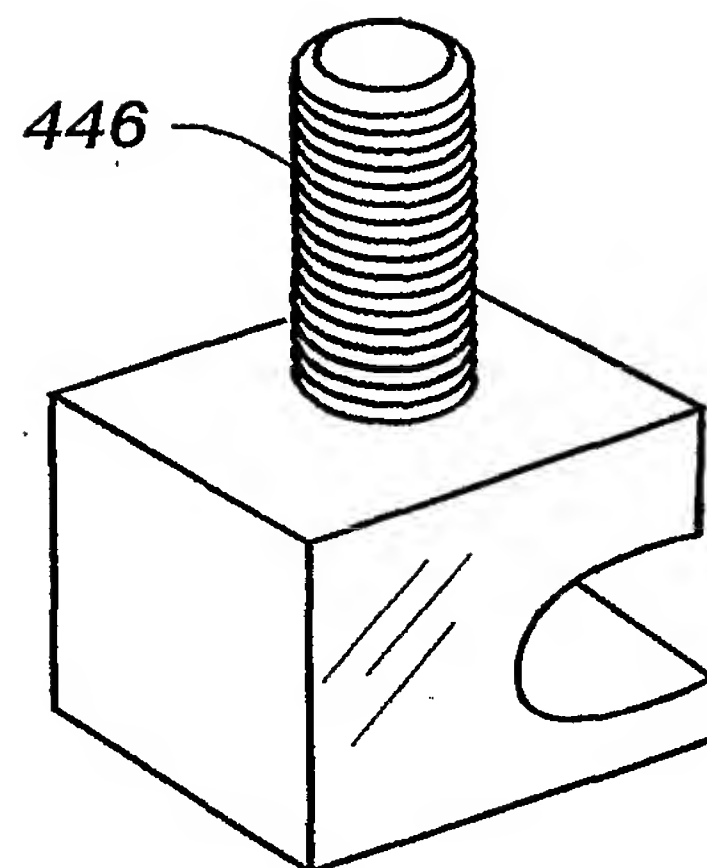


Fig - 4B

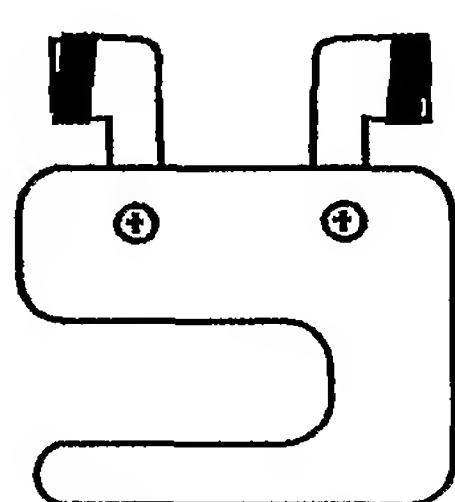


Fig - 4C

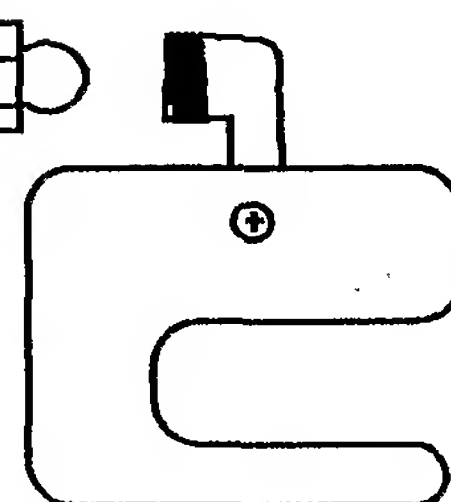


Fig - 4D

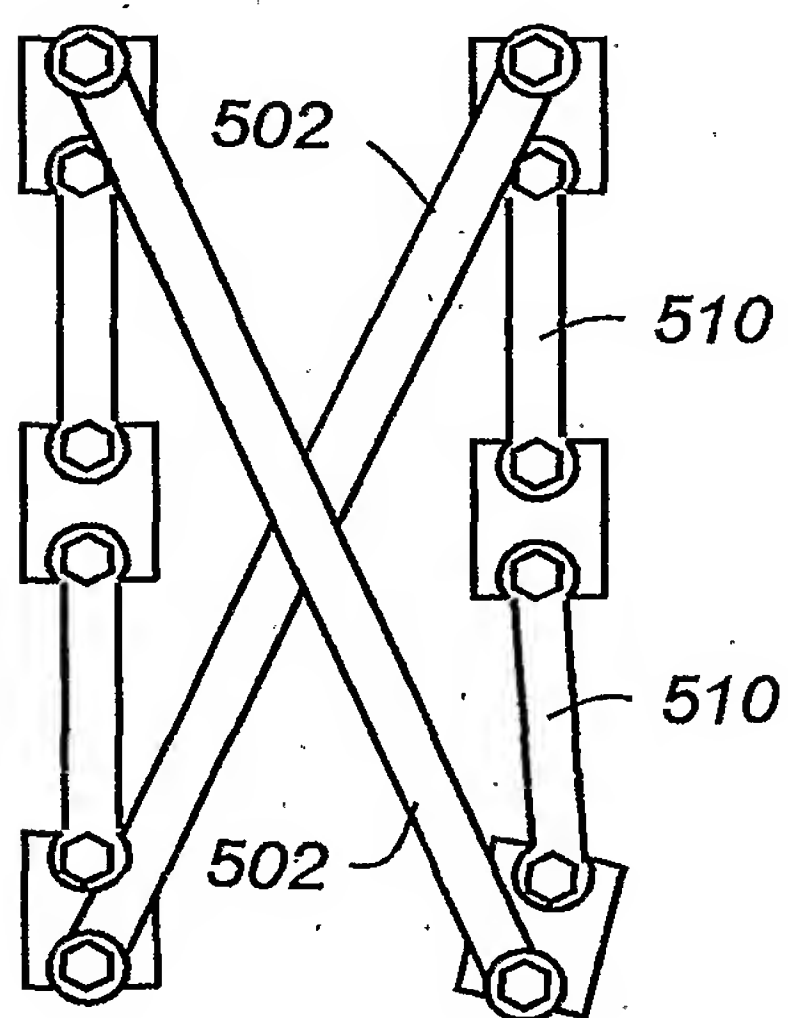


Fig - 5A

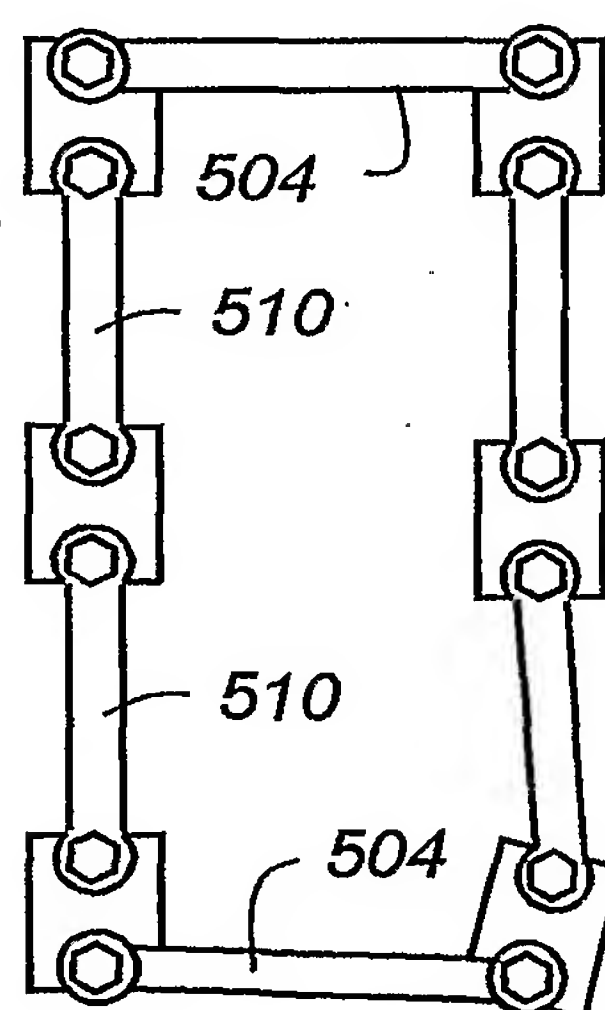
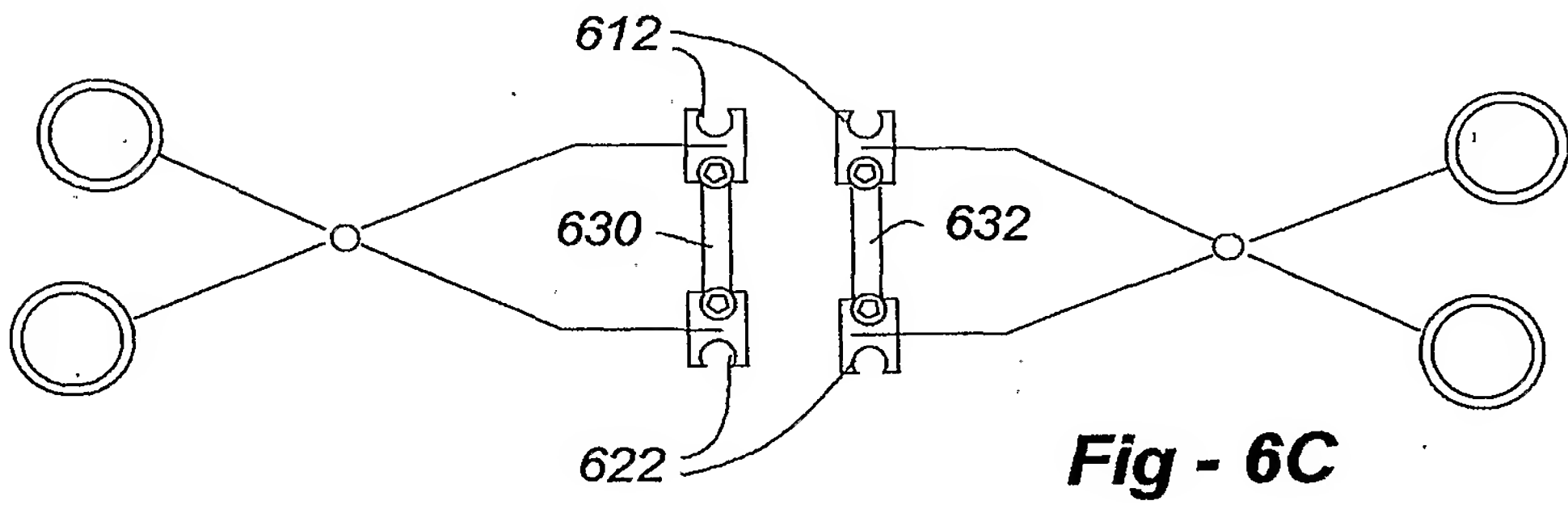
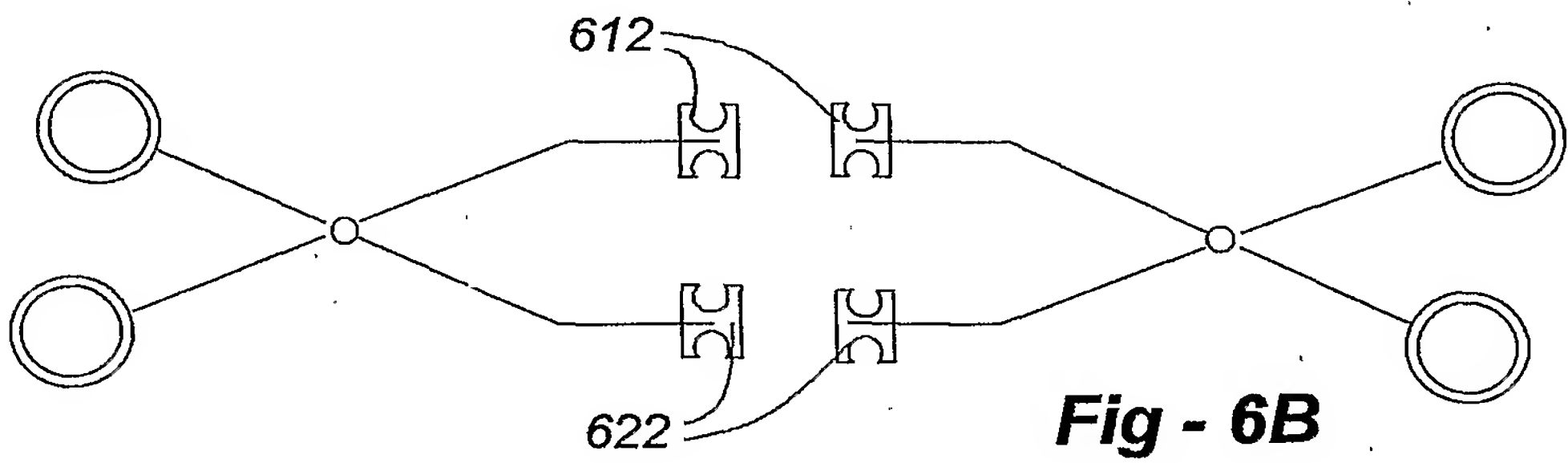
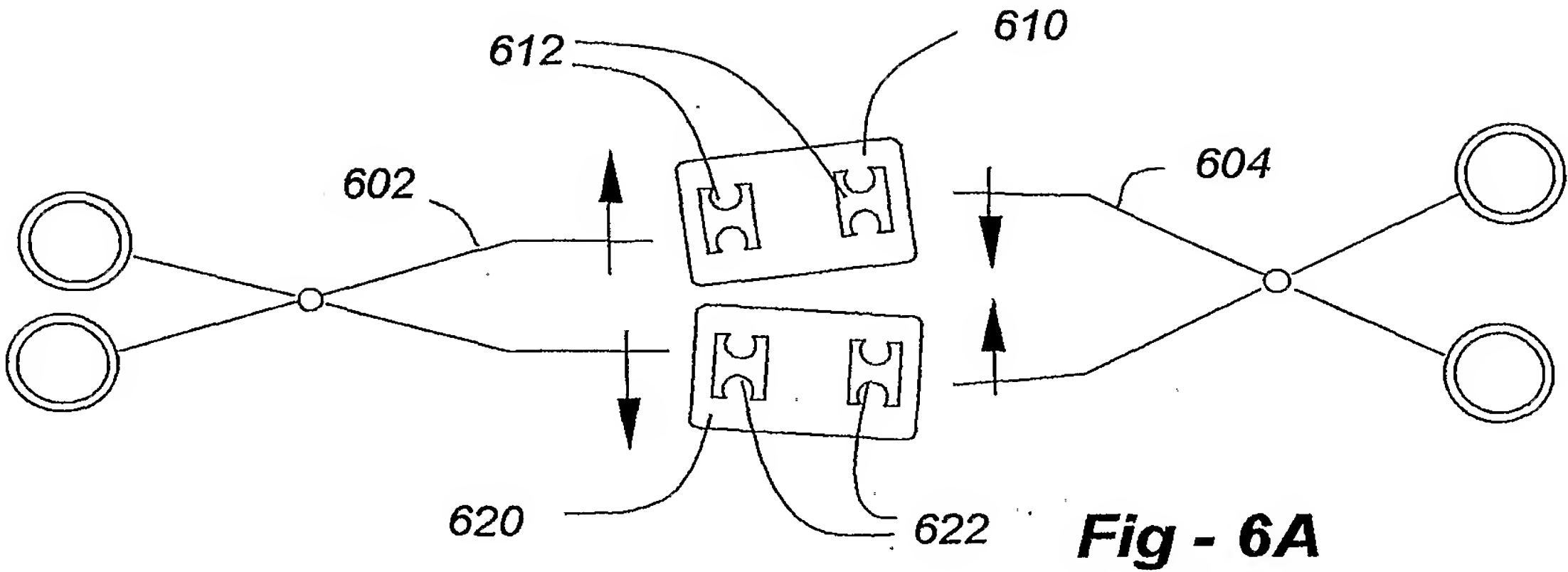


Fig - 5B



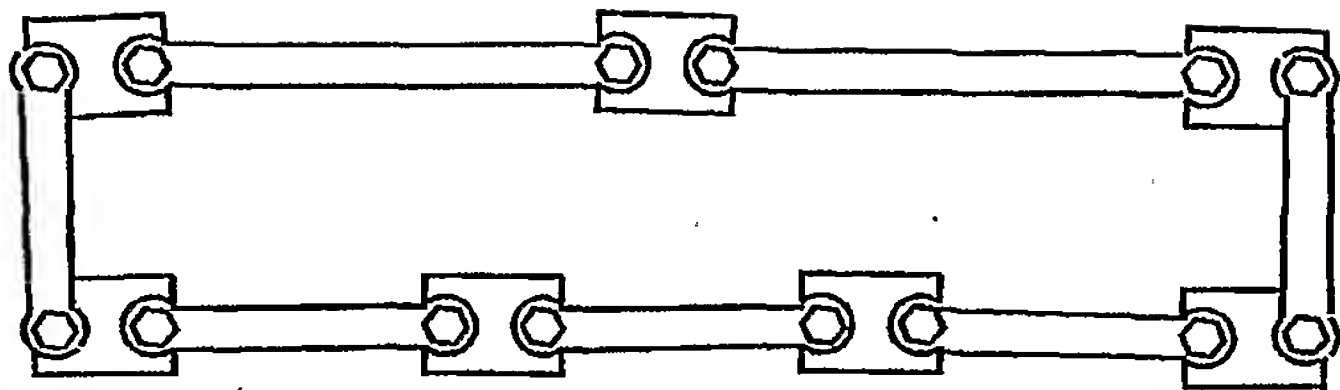


Fig - 7D

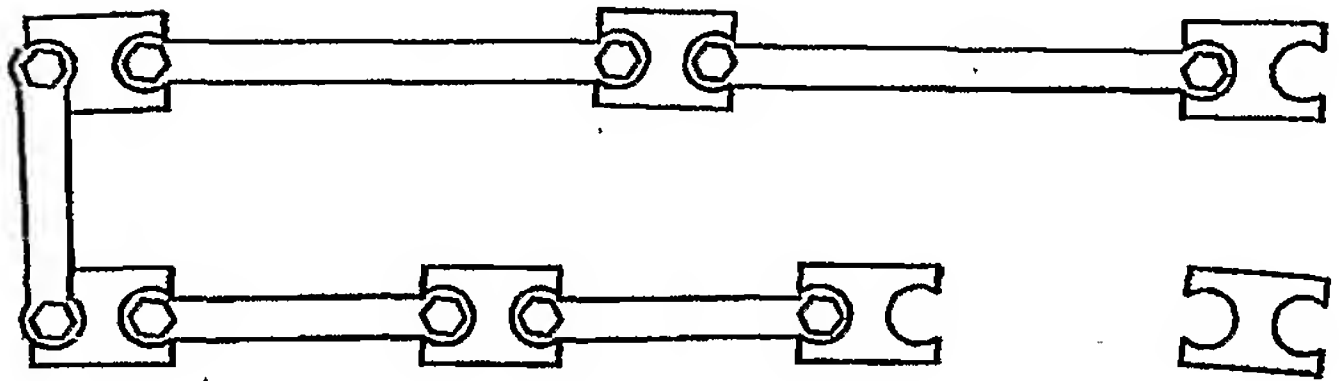


Fig - 7C

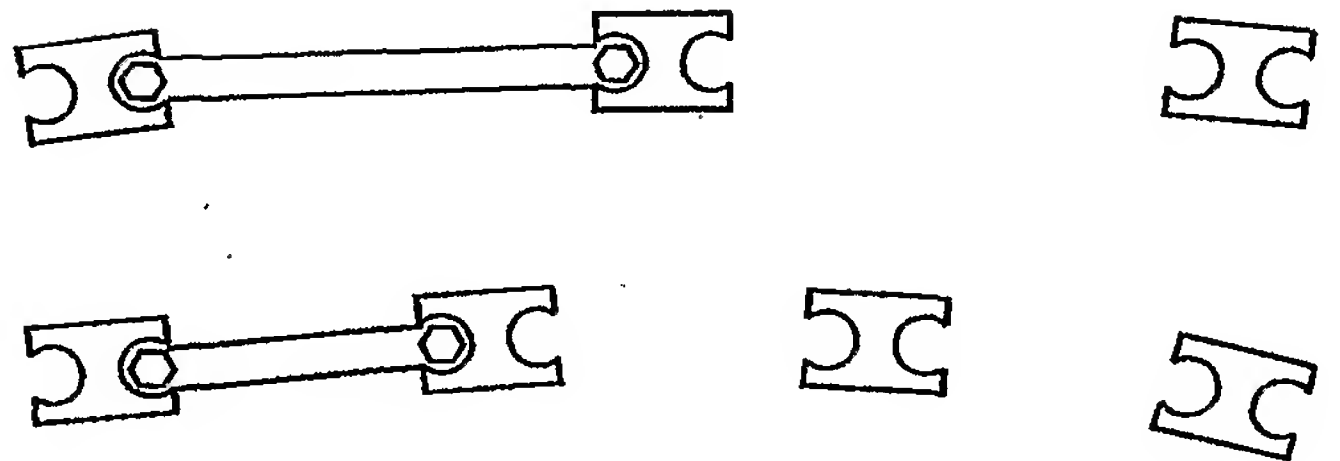


Fig - 7B

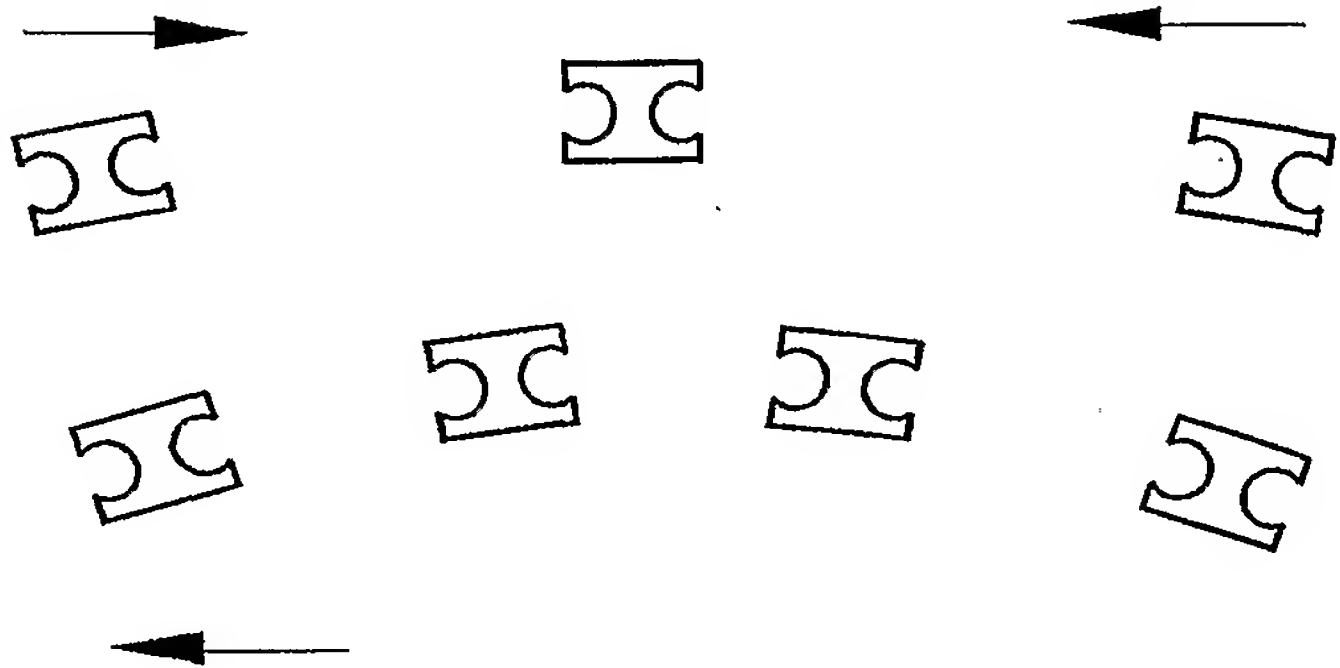
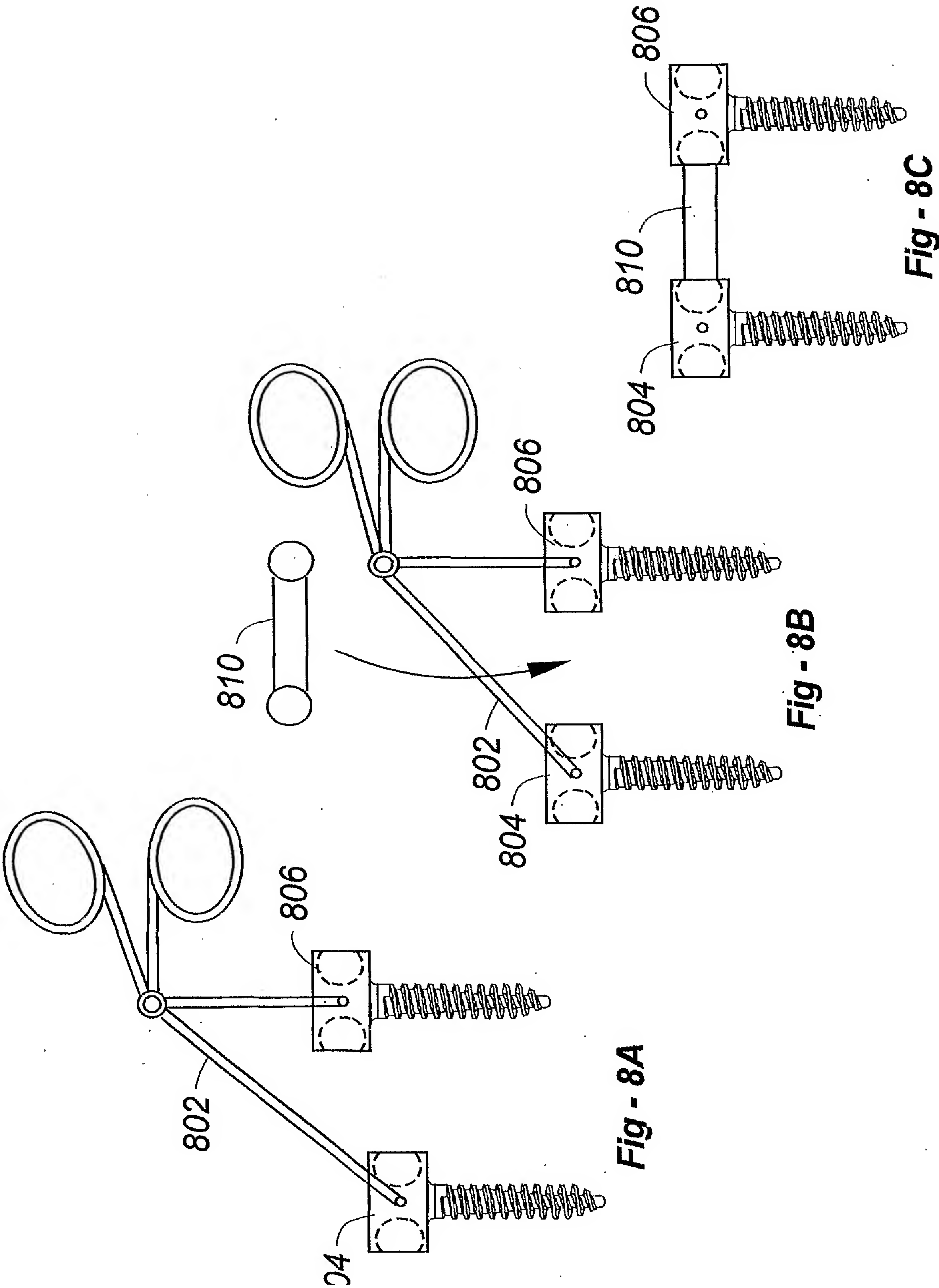
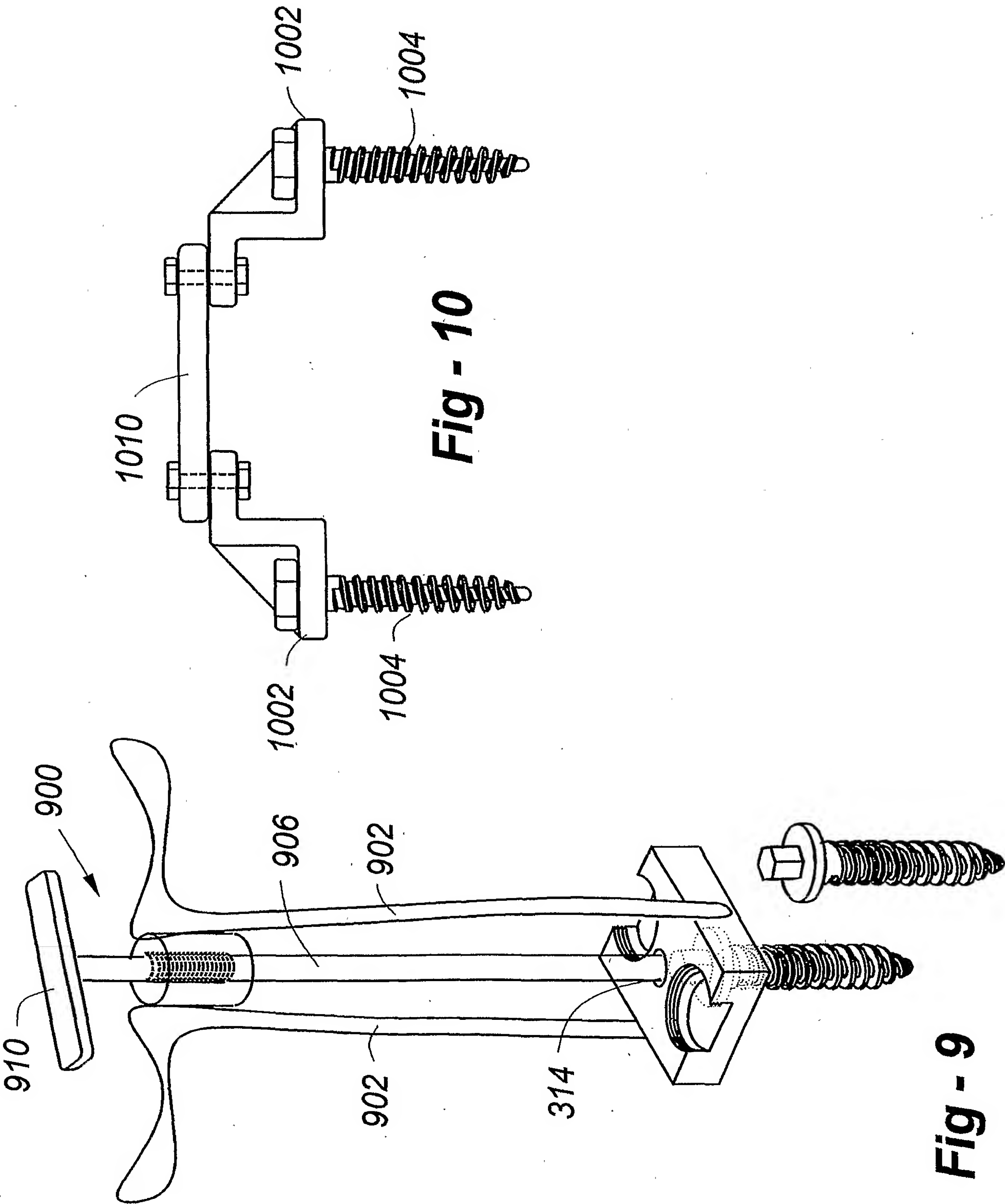


Fig - 7A





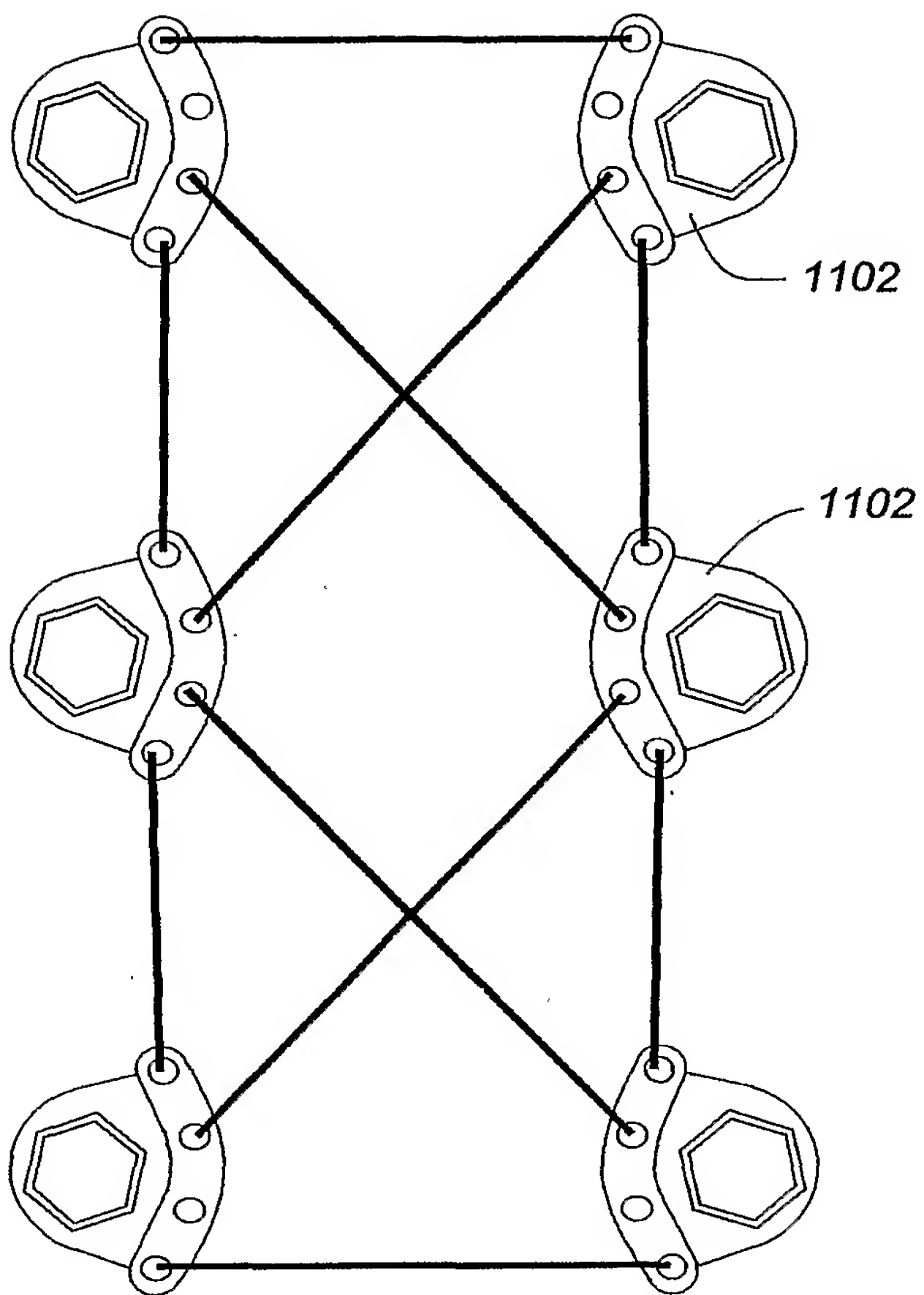


Fig - 11A

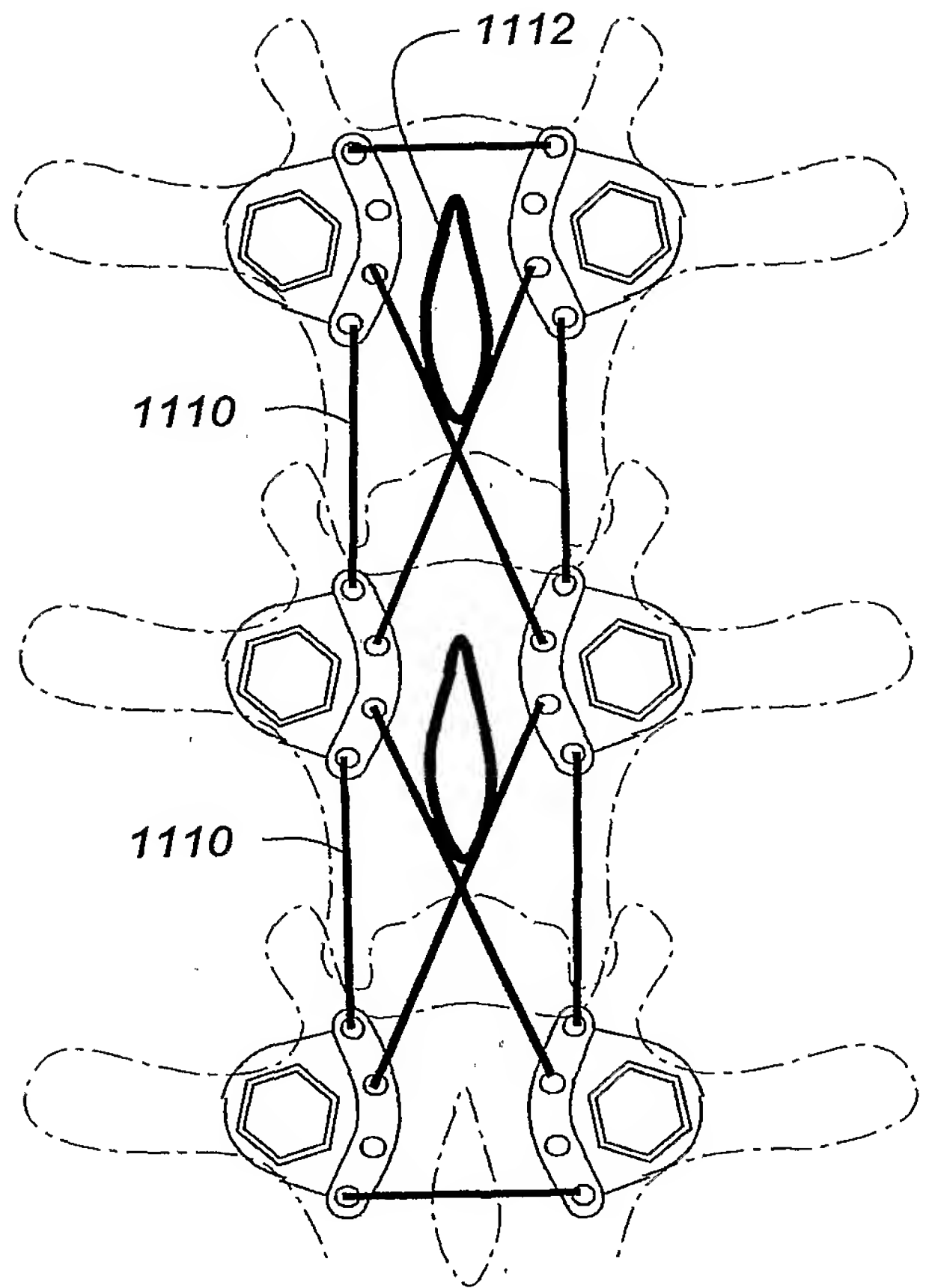


Fig - 11B

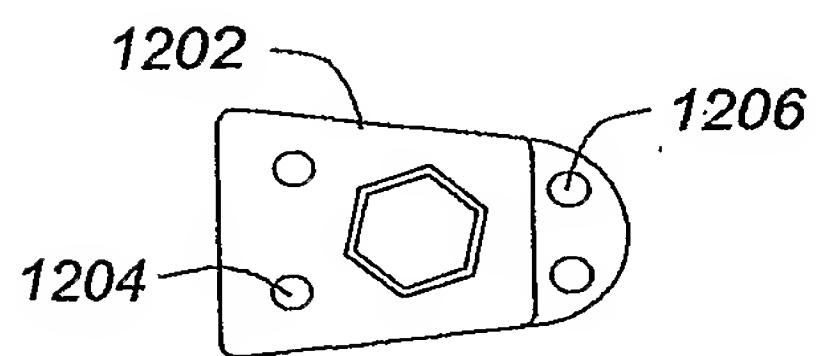


Fig - 12A

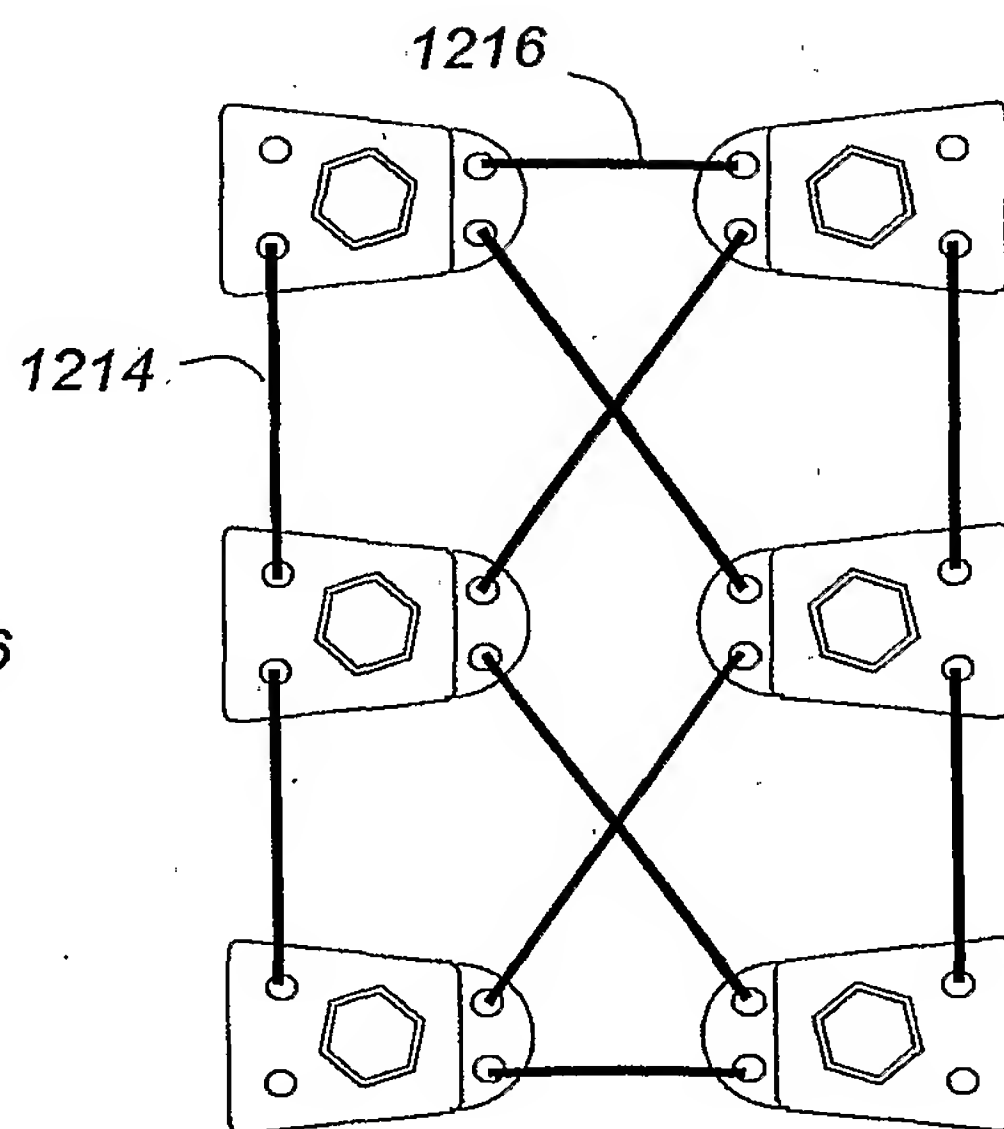


Fig - 12B

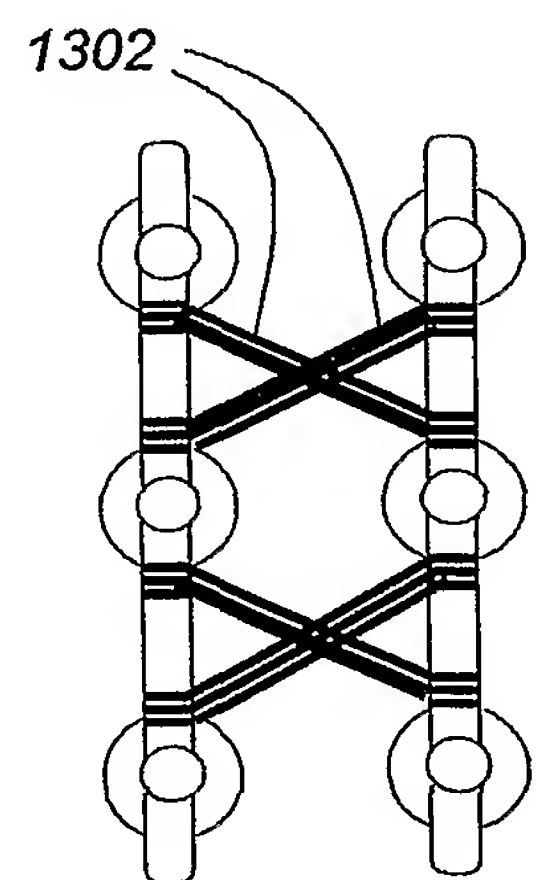


Fig - 13

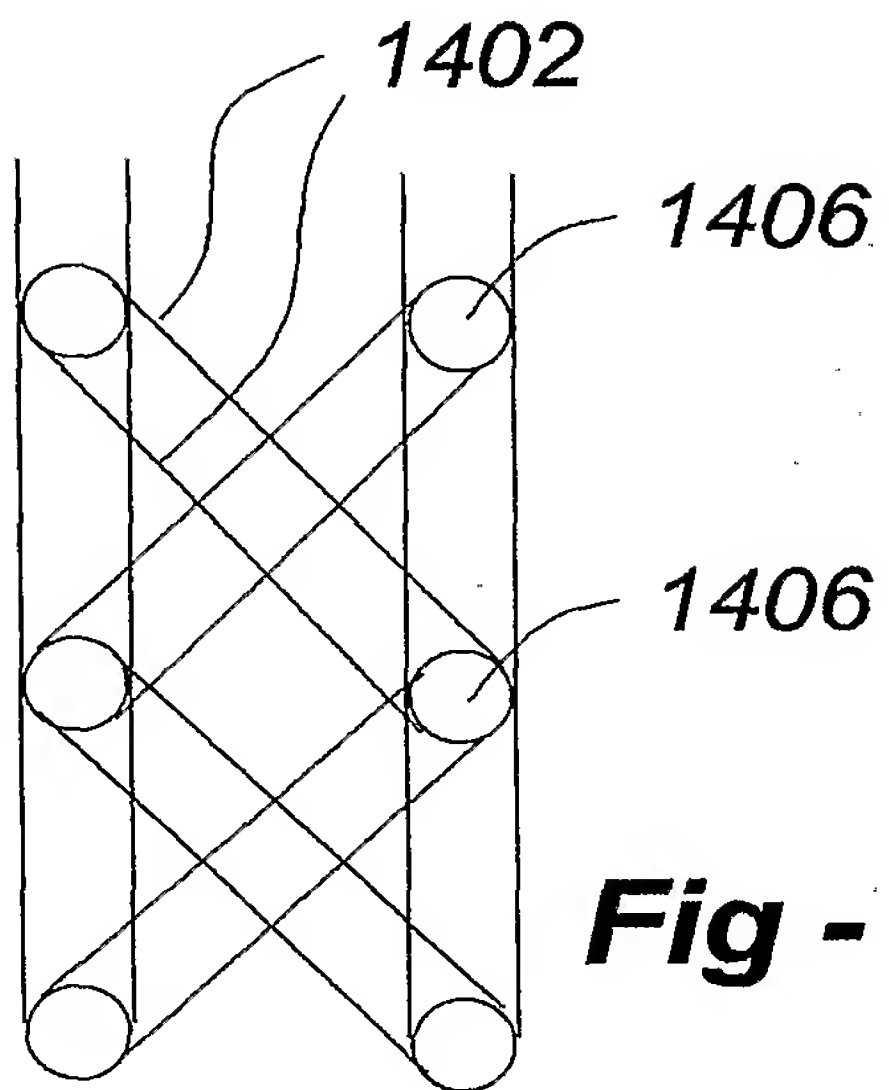


Fig - 14

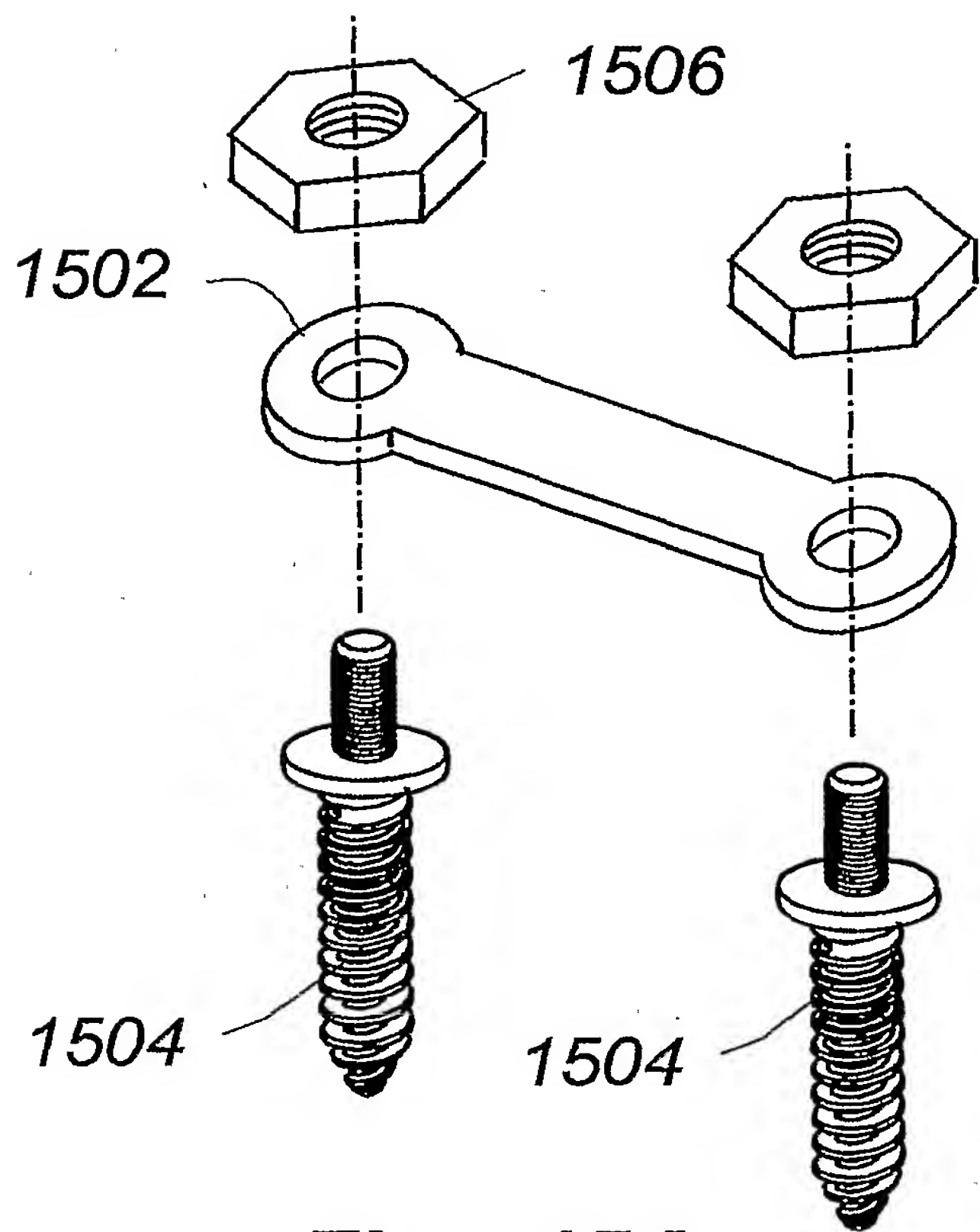


Fig - 15A

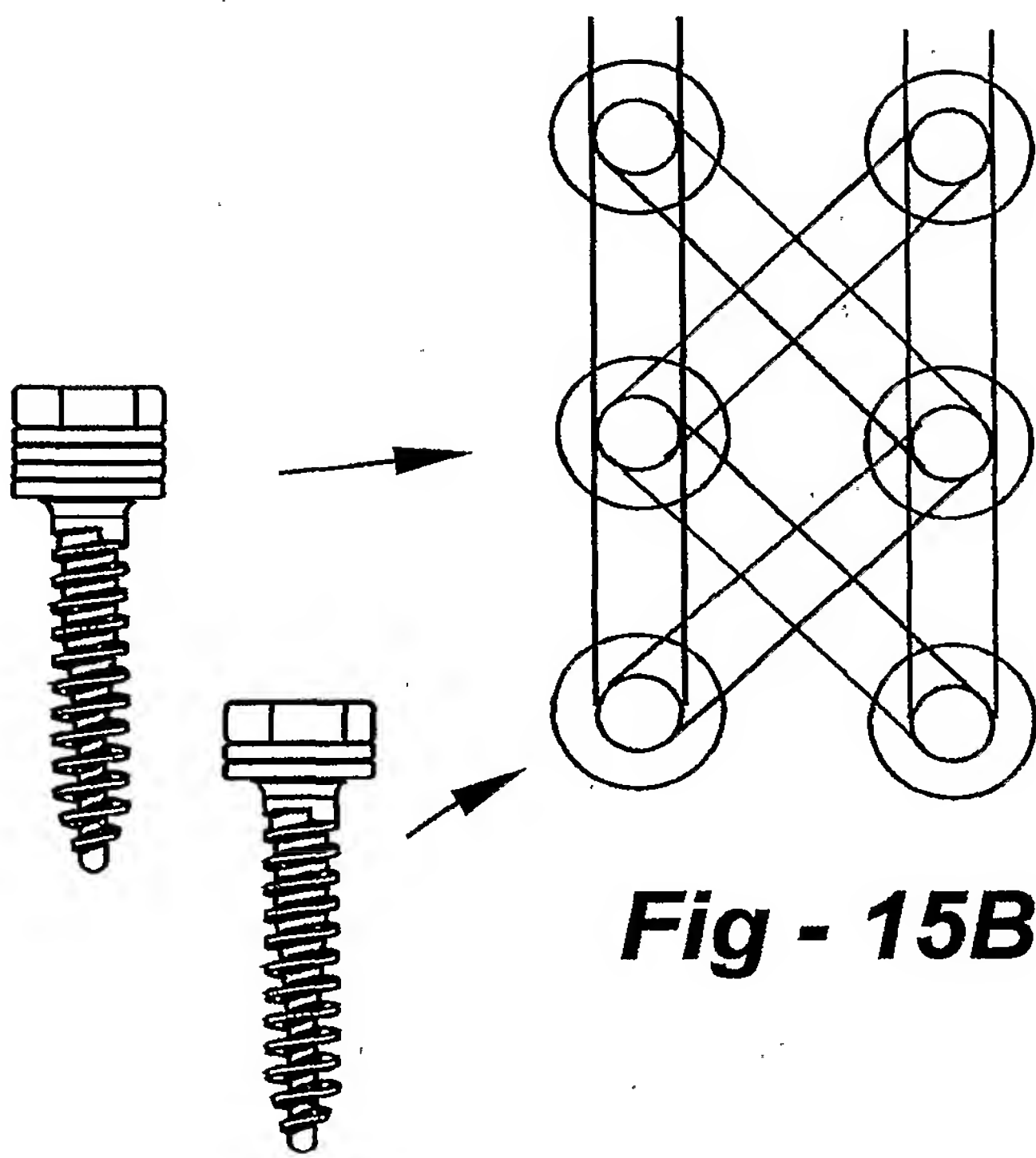


Fig - 15B

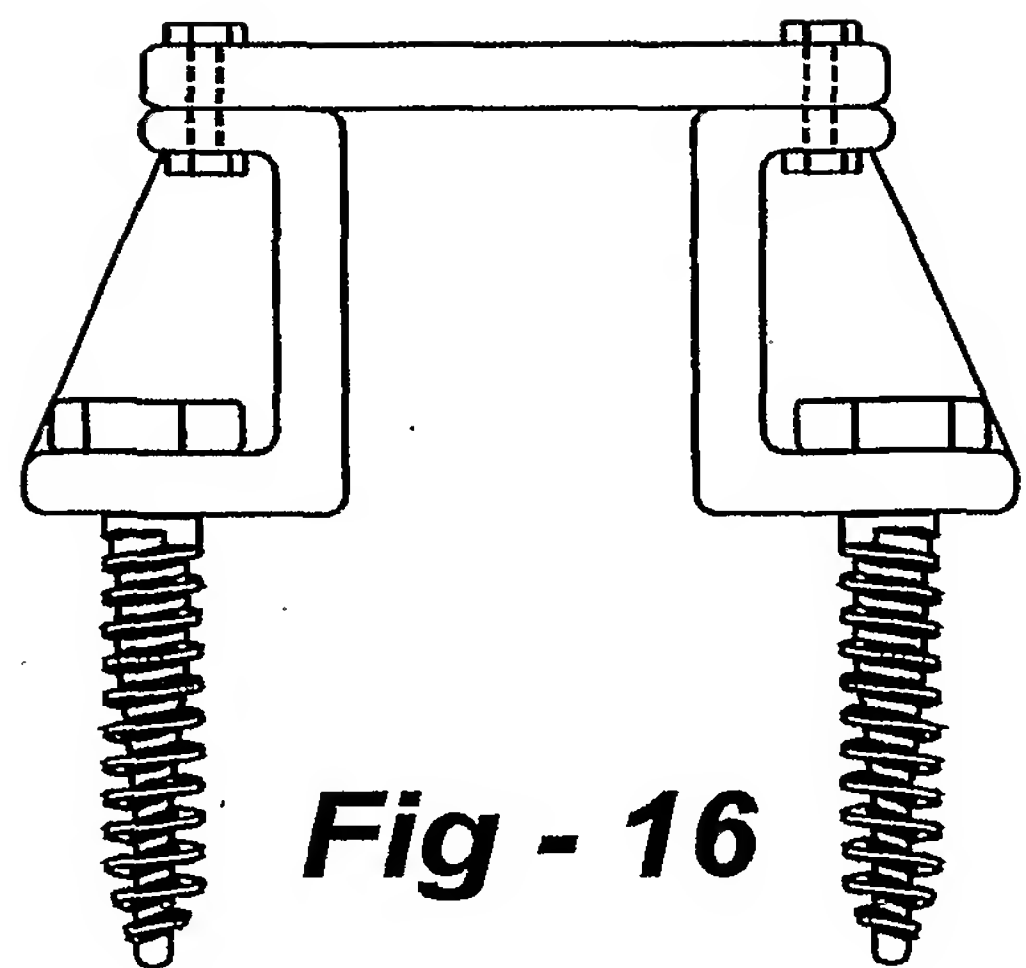


Fig - 16

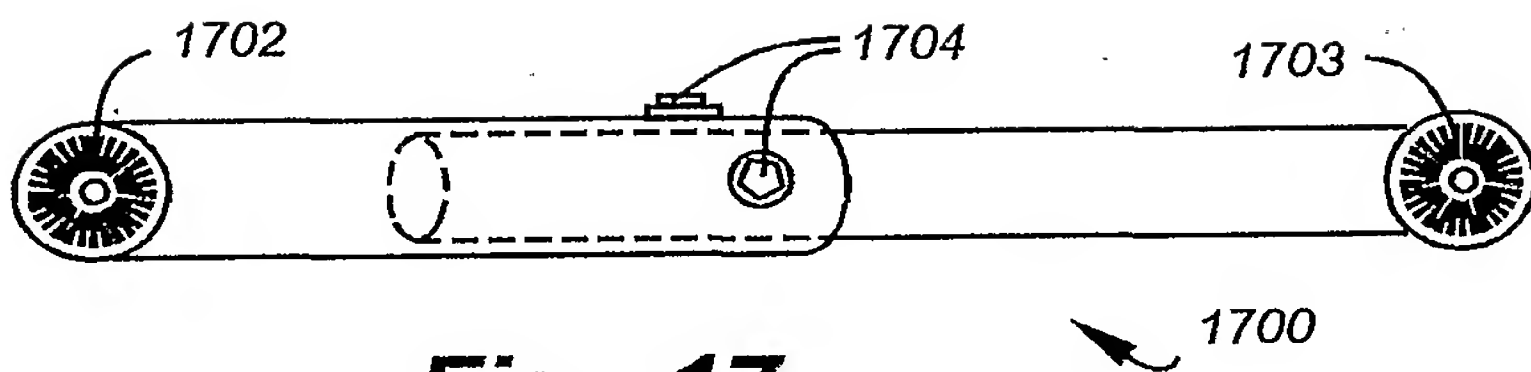


Fig - 17

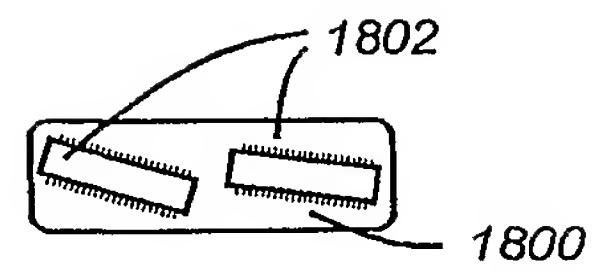


Fig - 18B

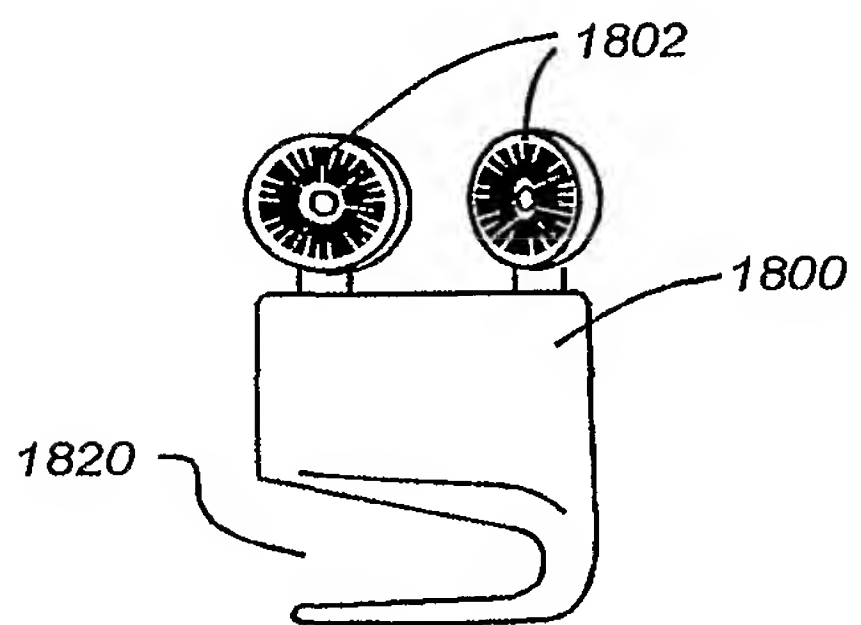


Fig - 18A

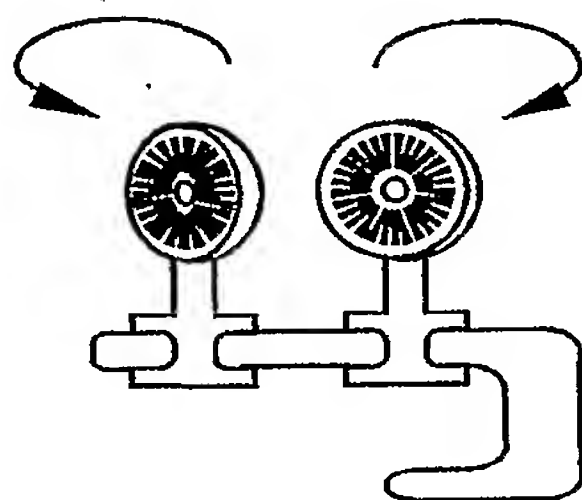


Fig - 18C

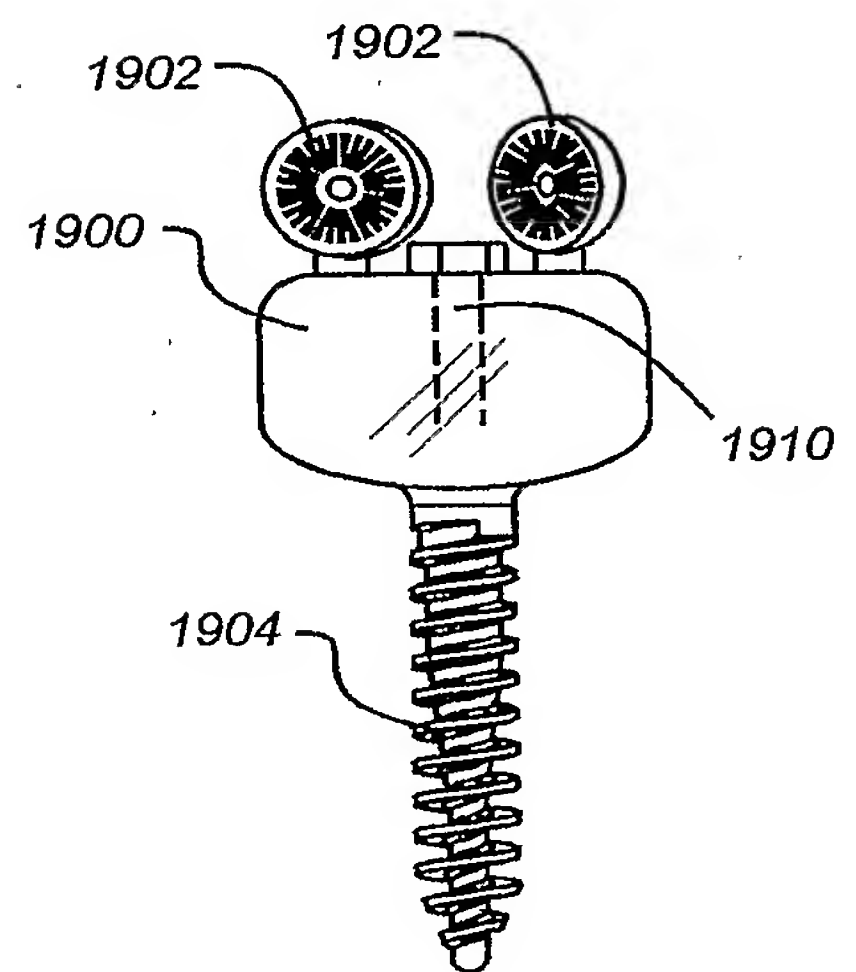


Fig - 19

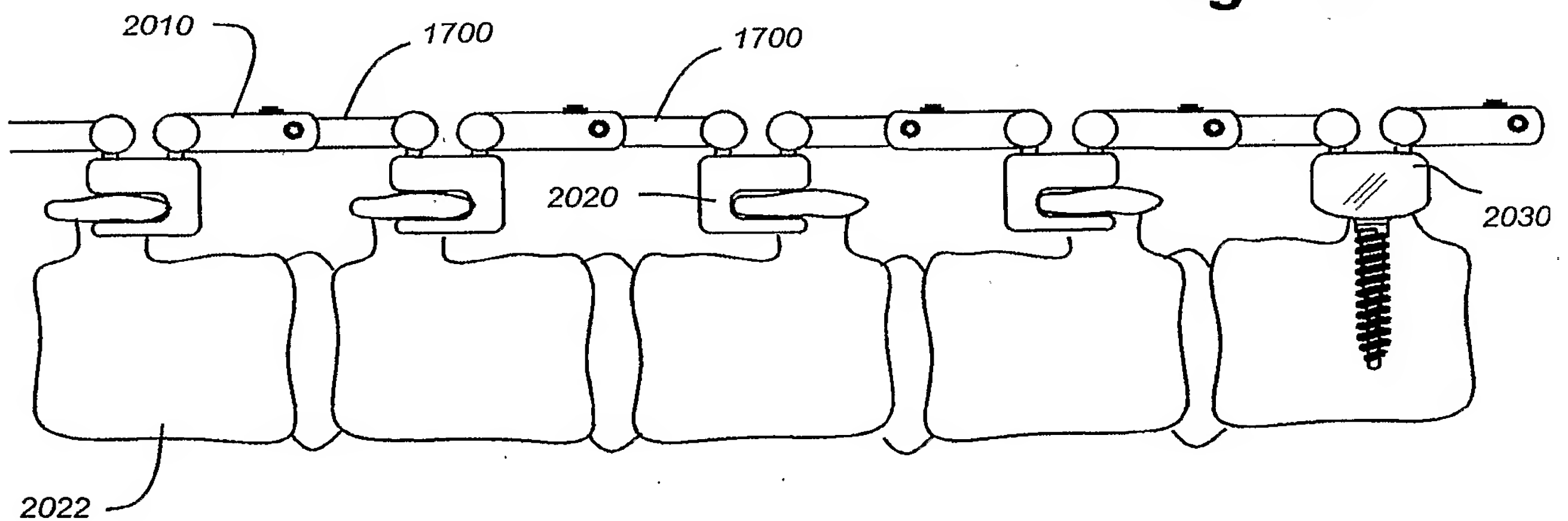


Fig - 20

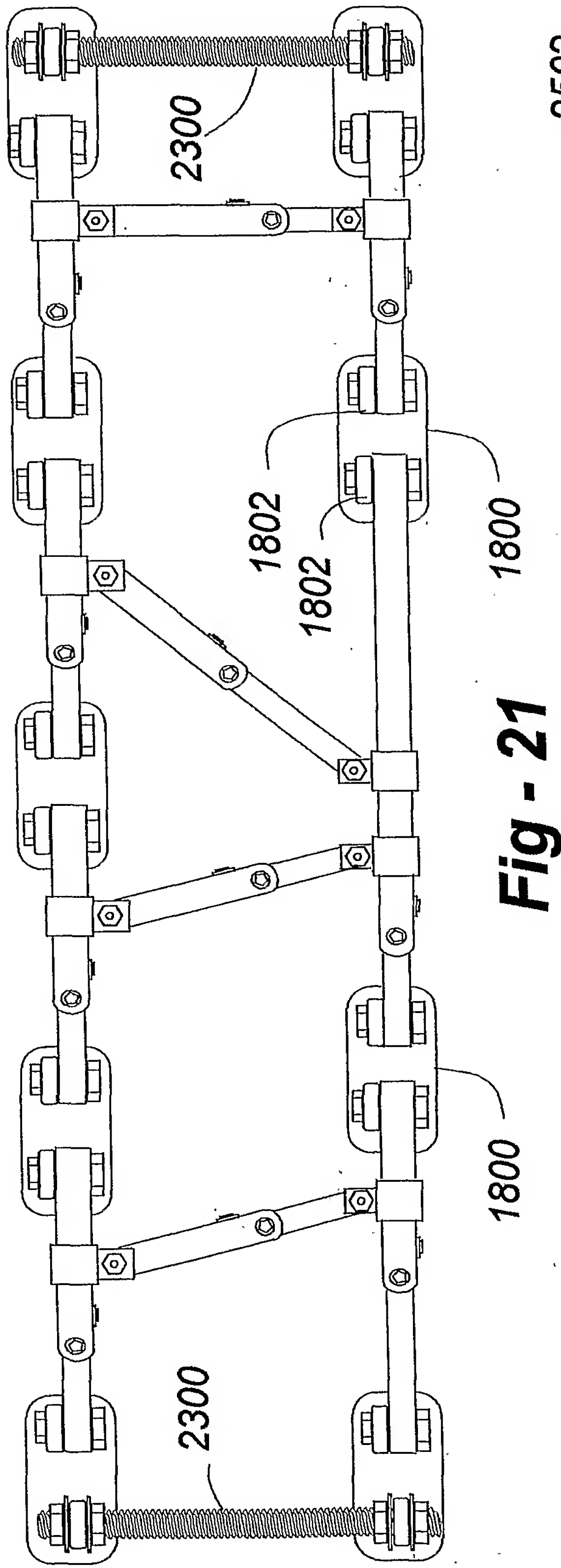


Fig - 21

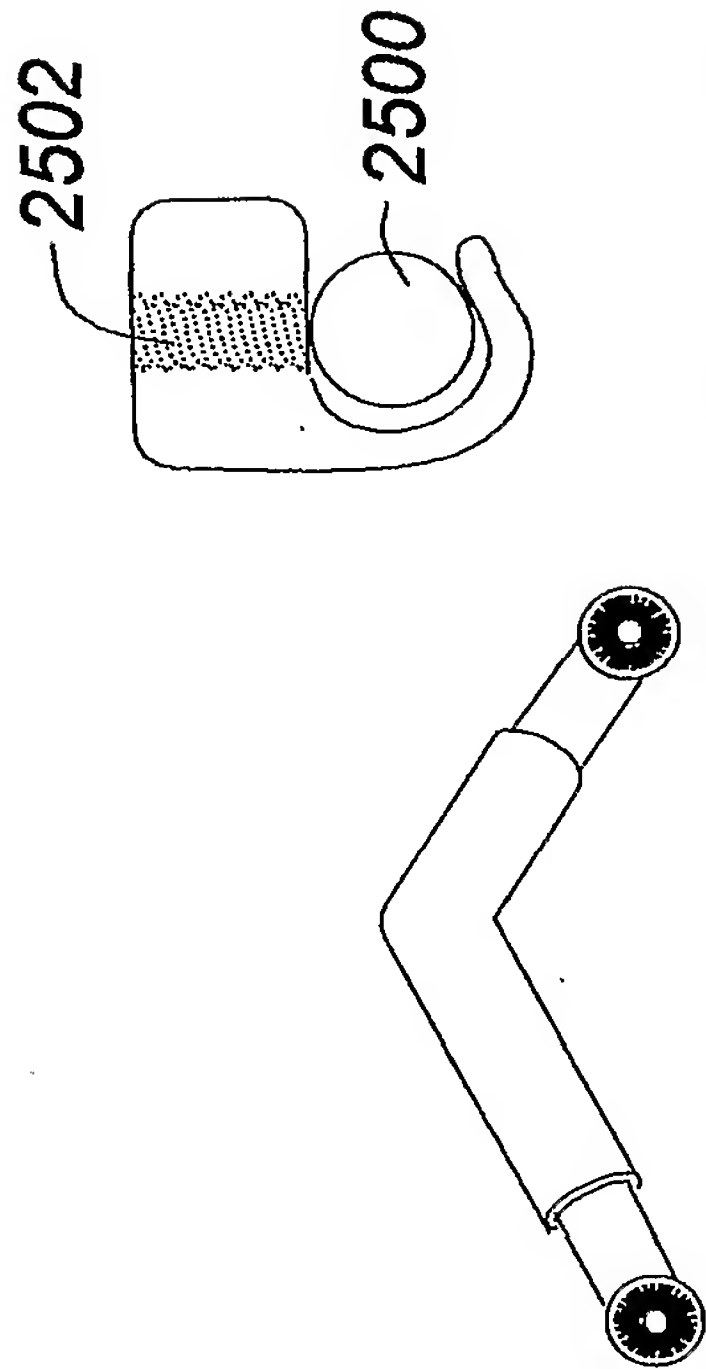


Fig - 24

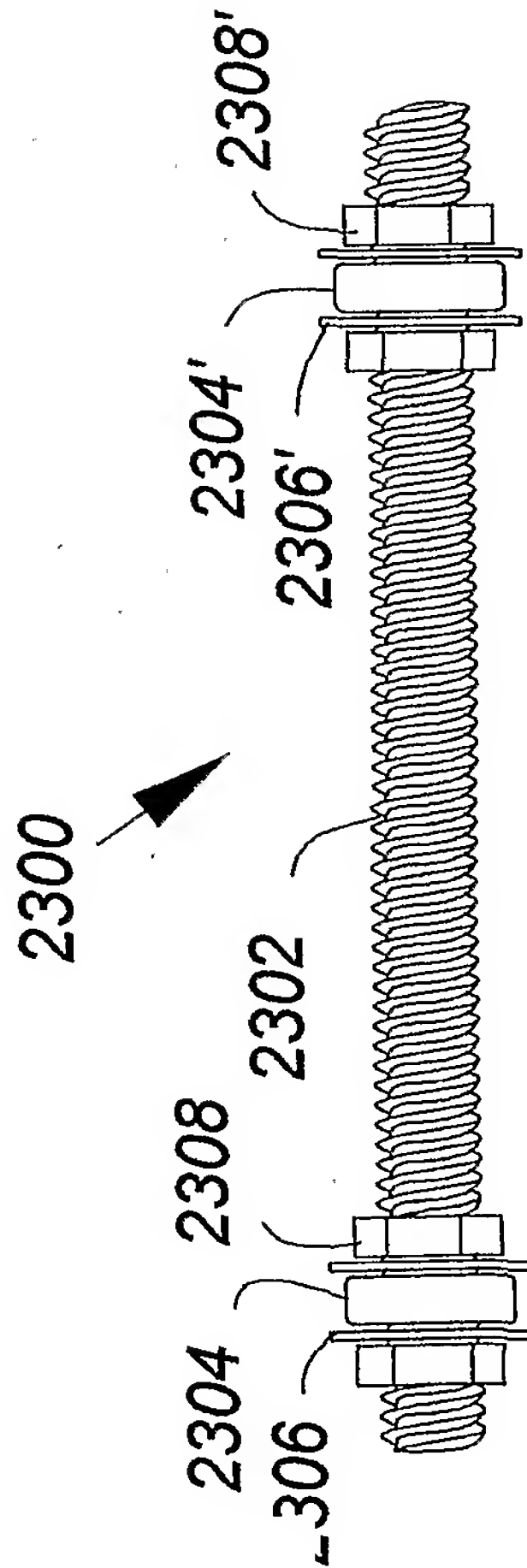
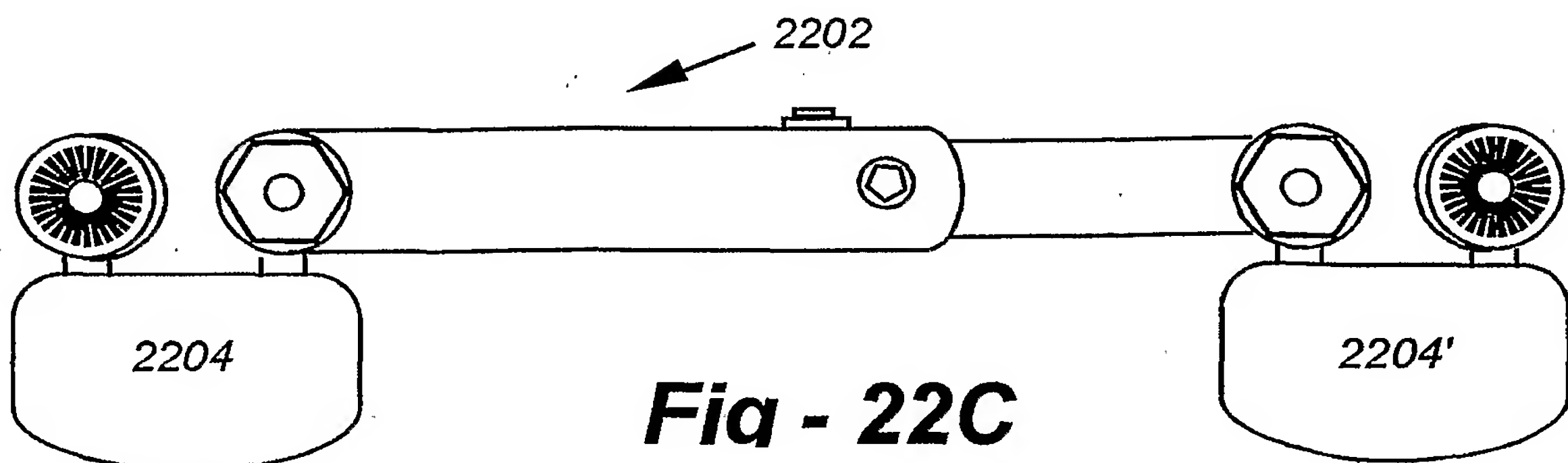
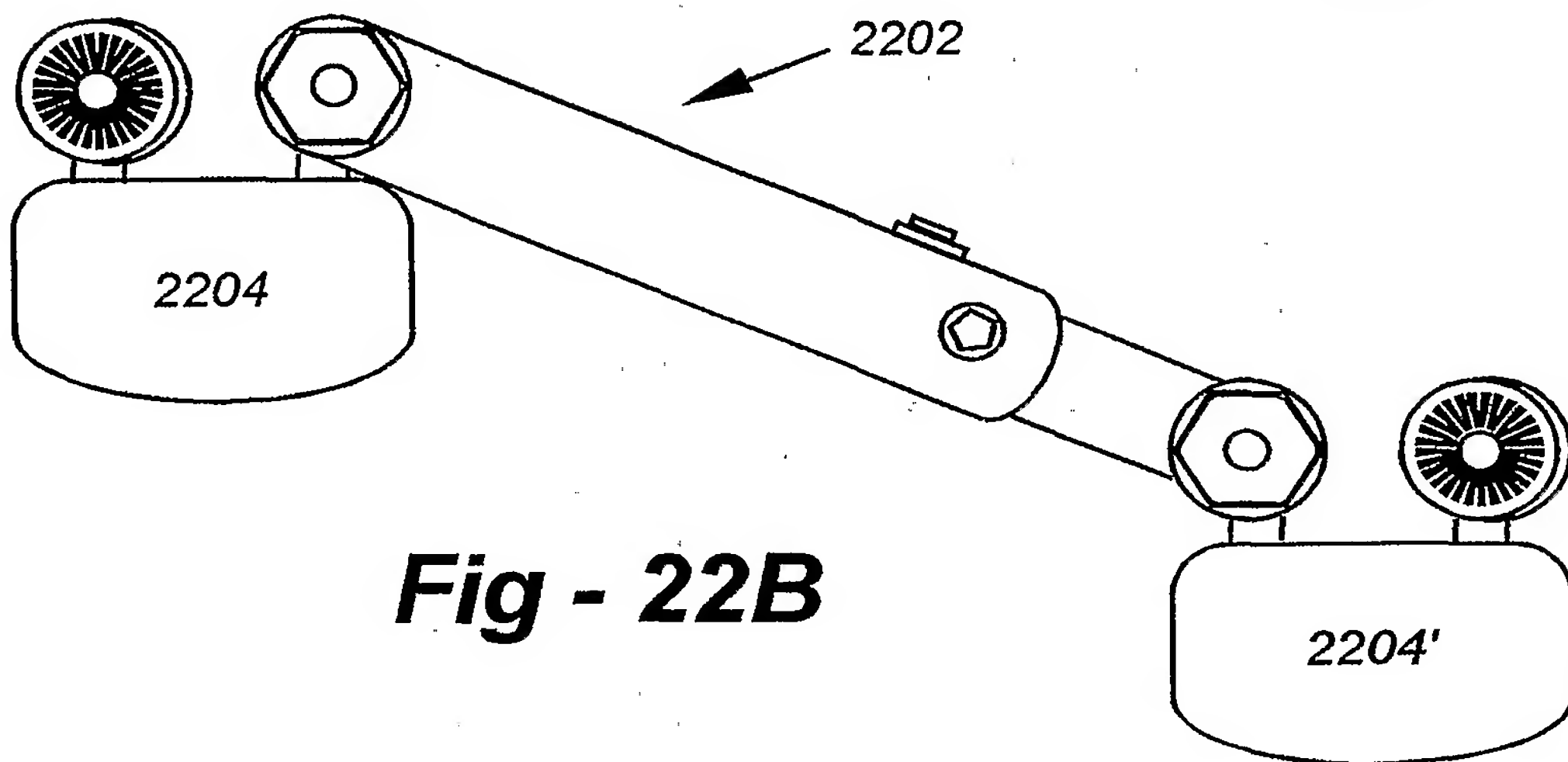
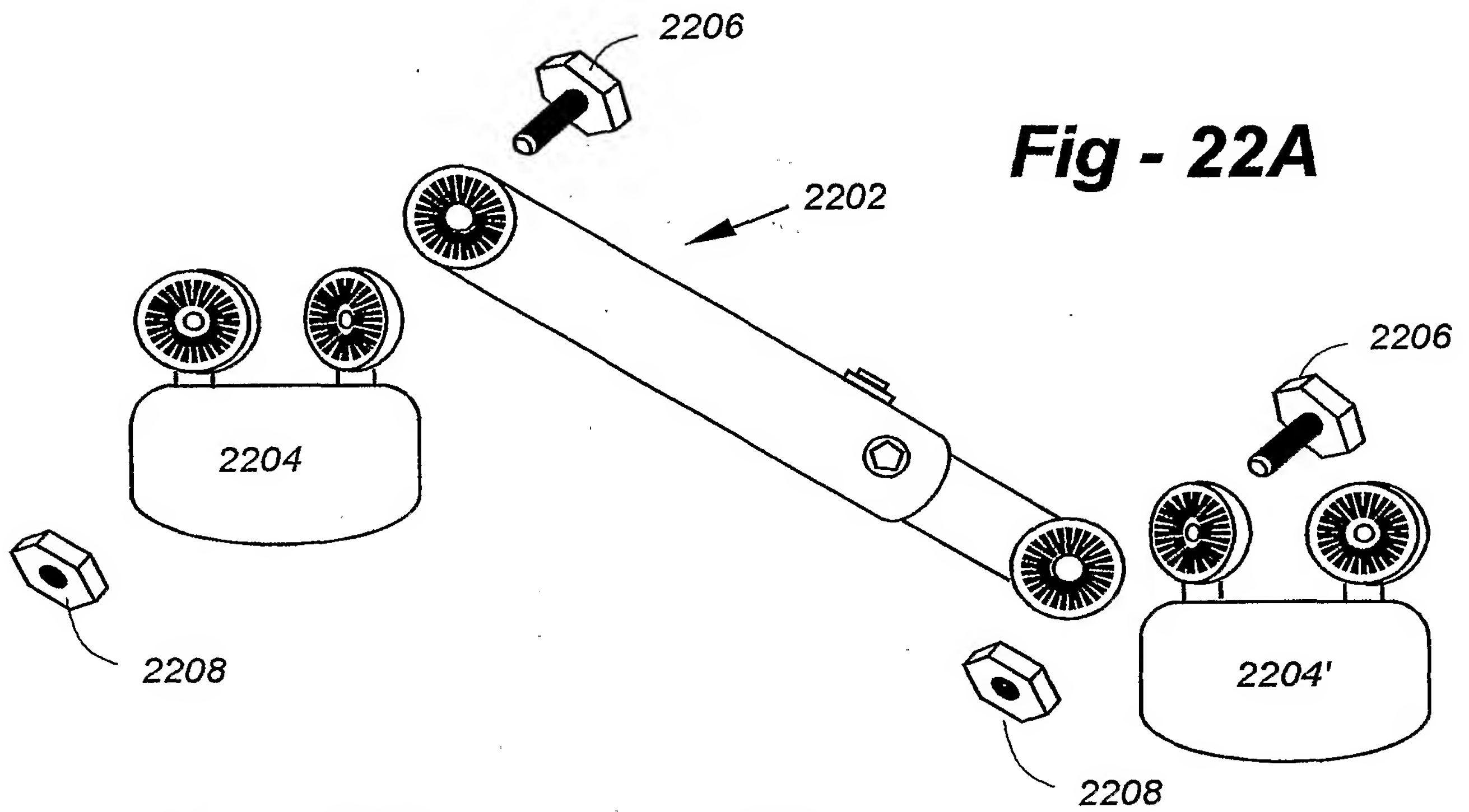


Fig - 23



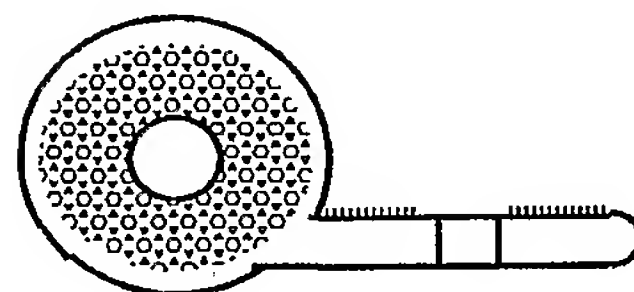
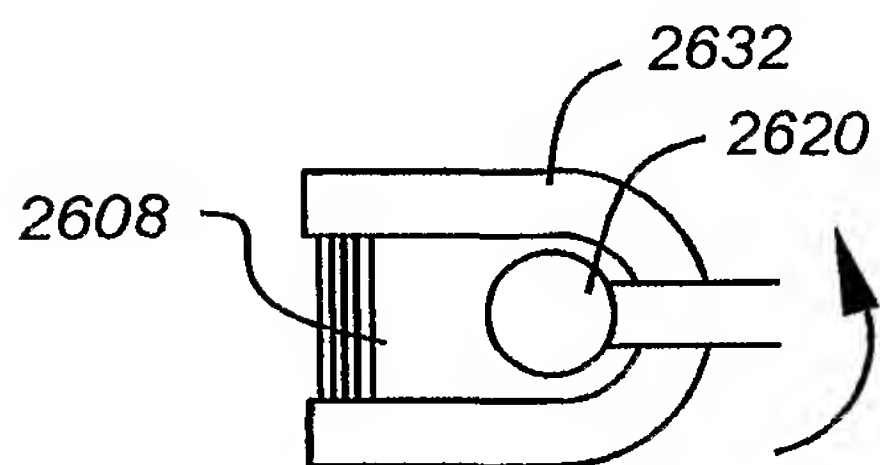
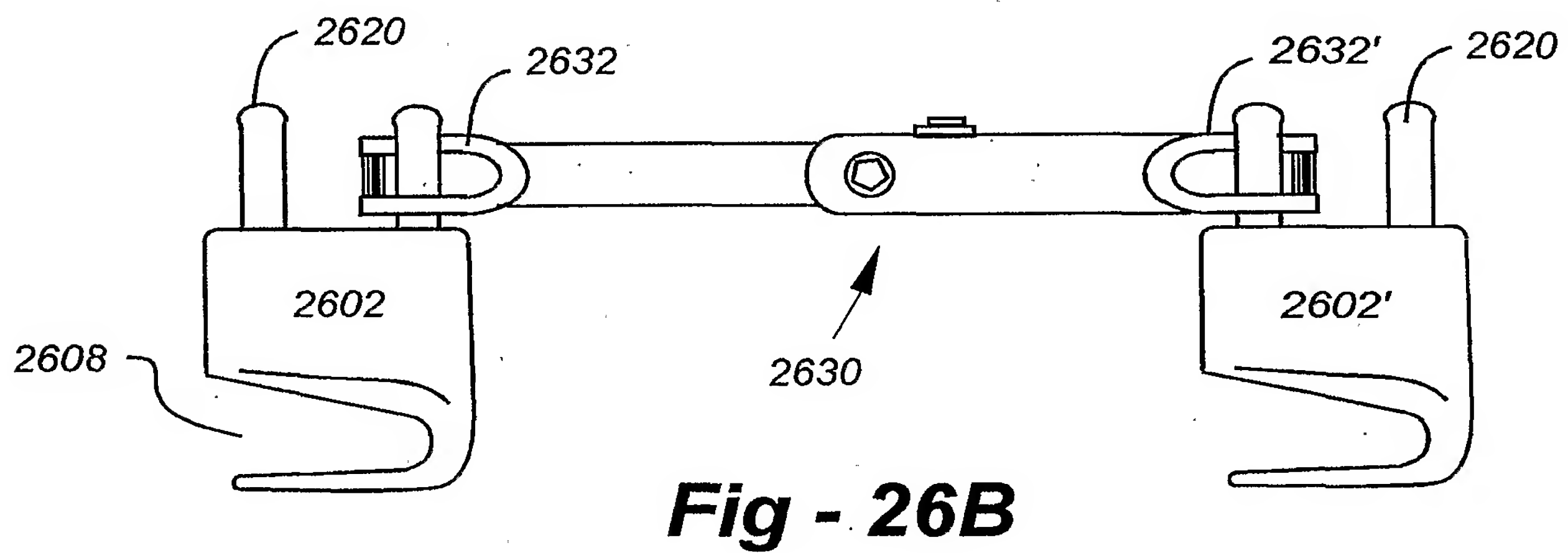
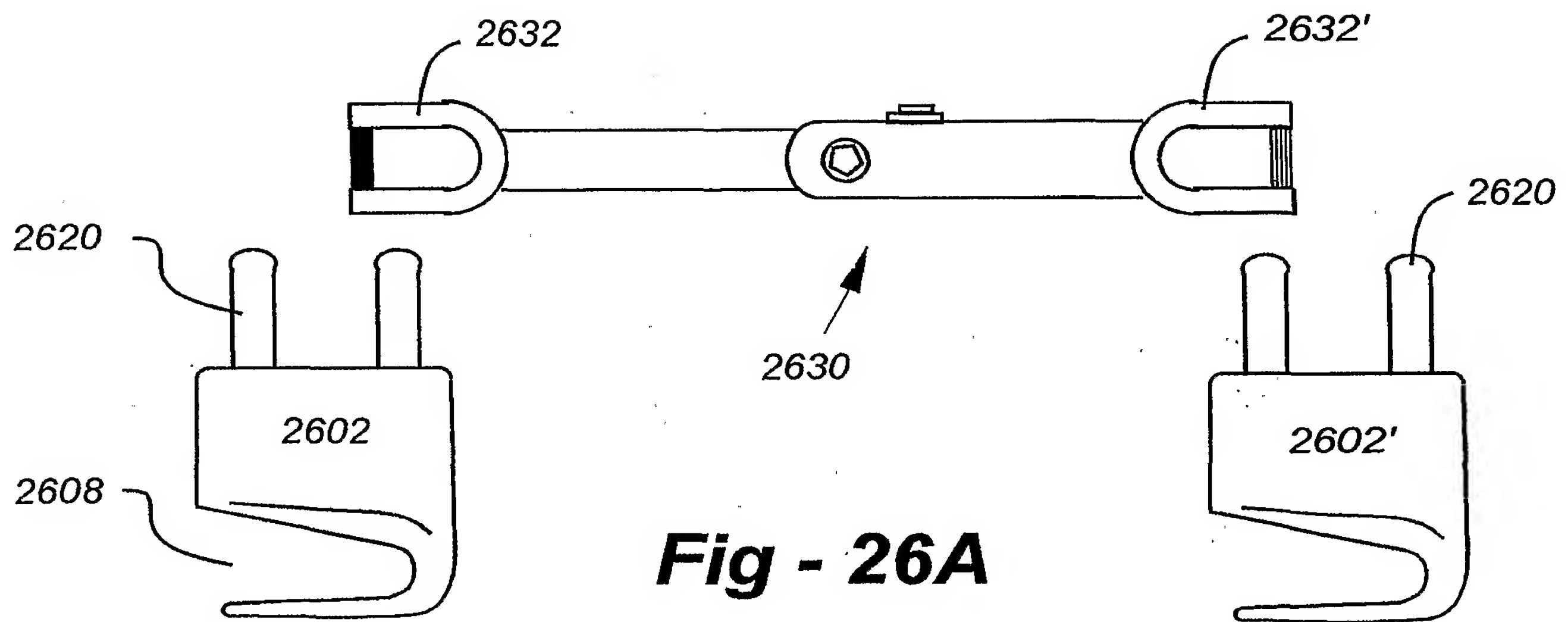


Fig - 27

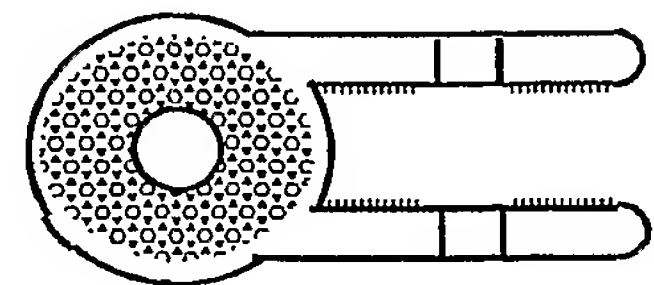


Fig - 28

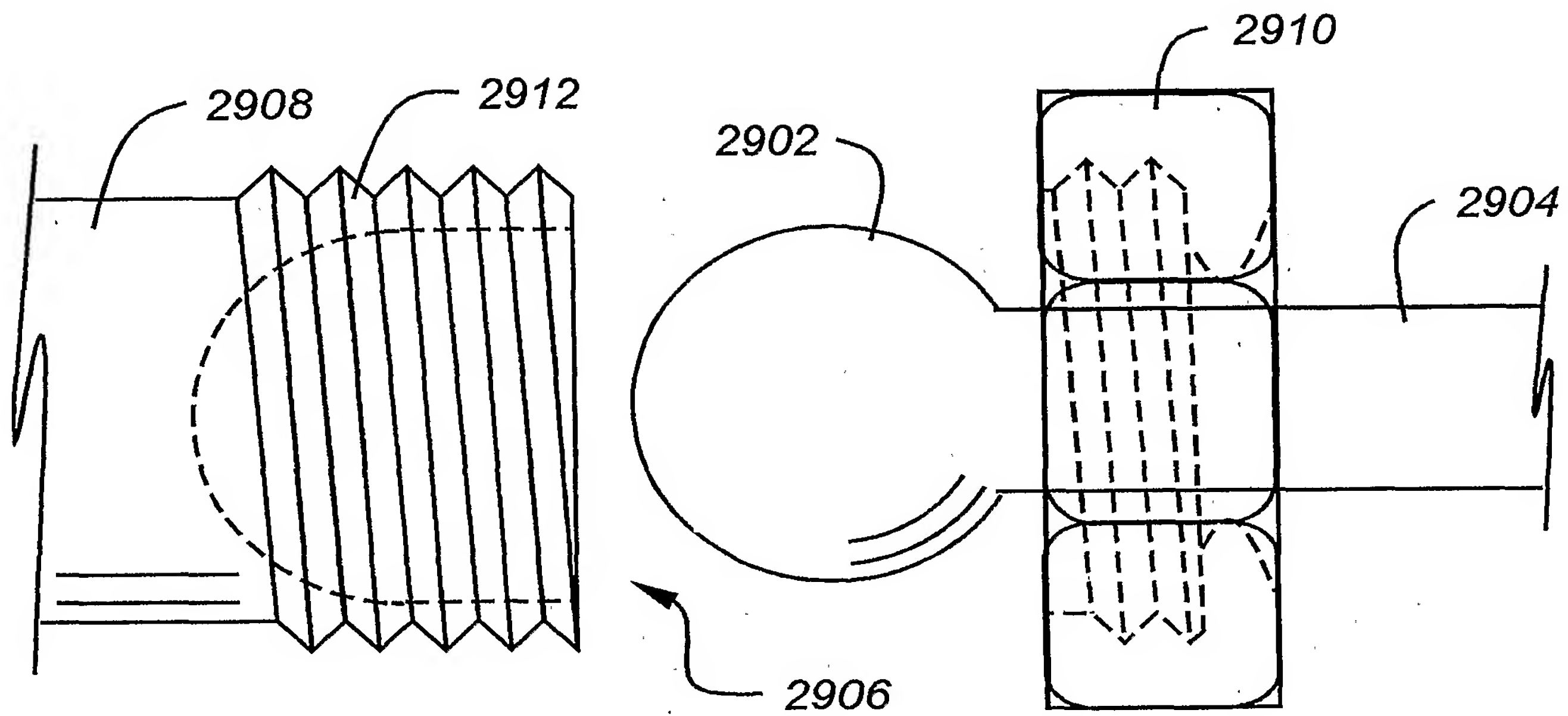


Fig - 29A

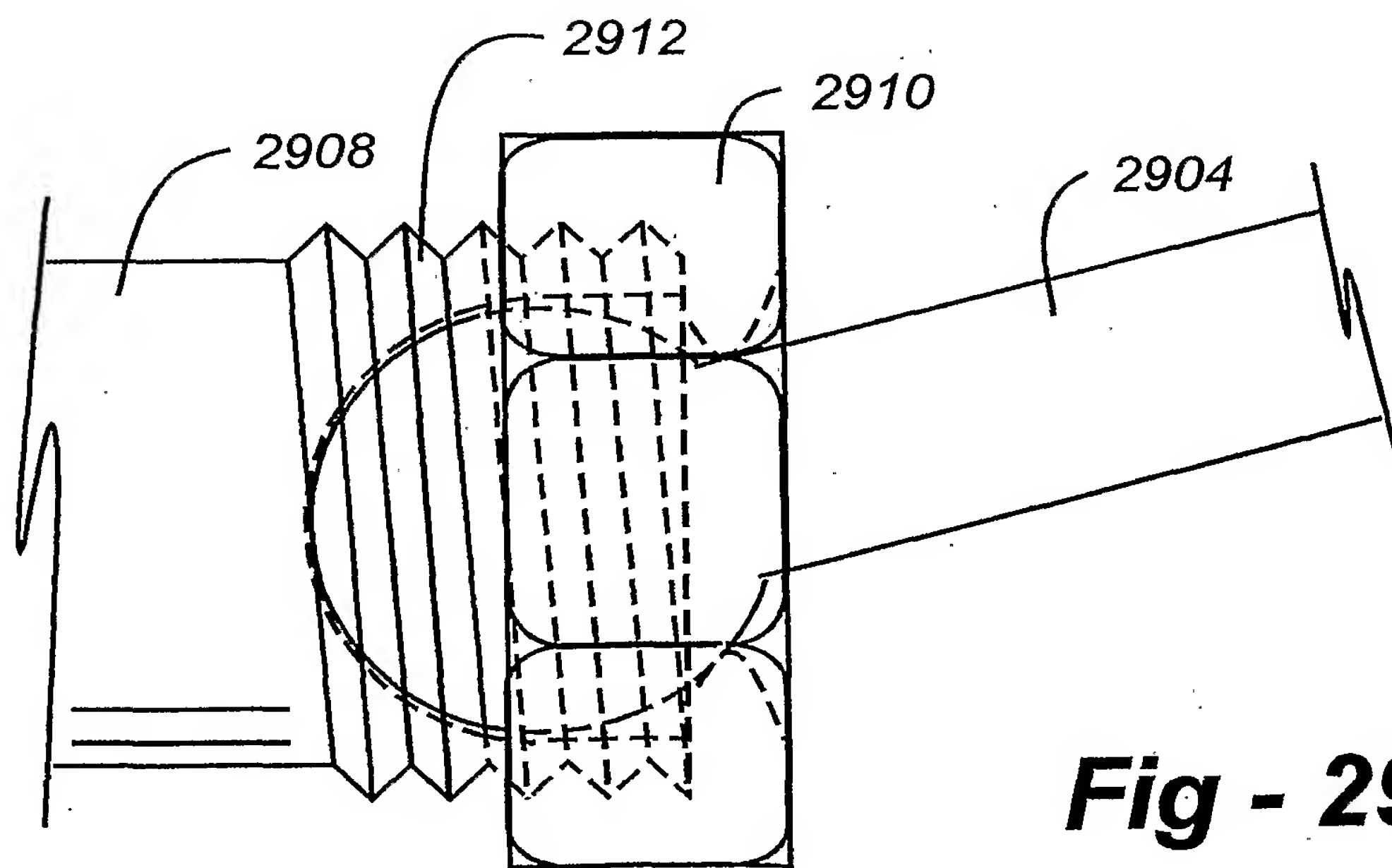
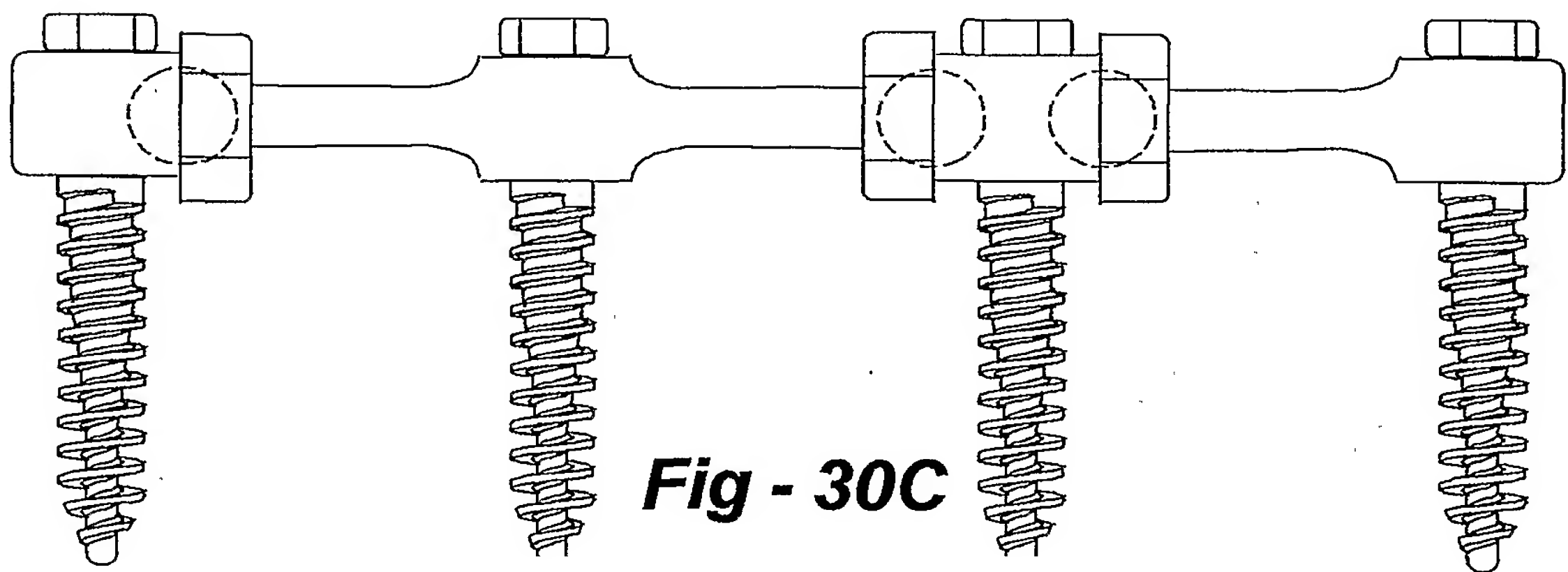
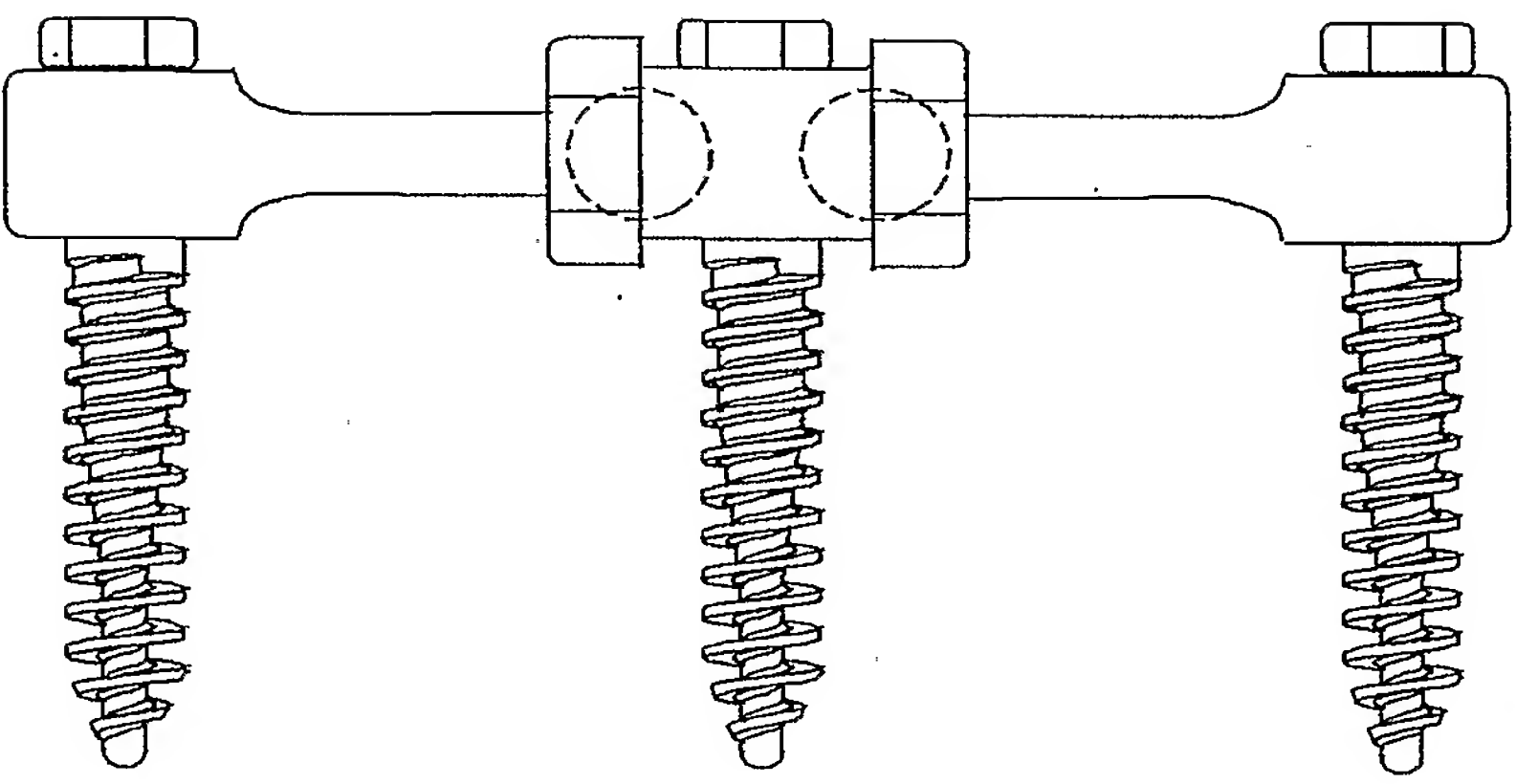
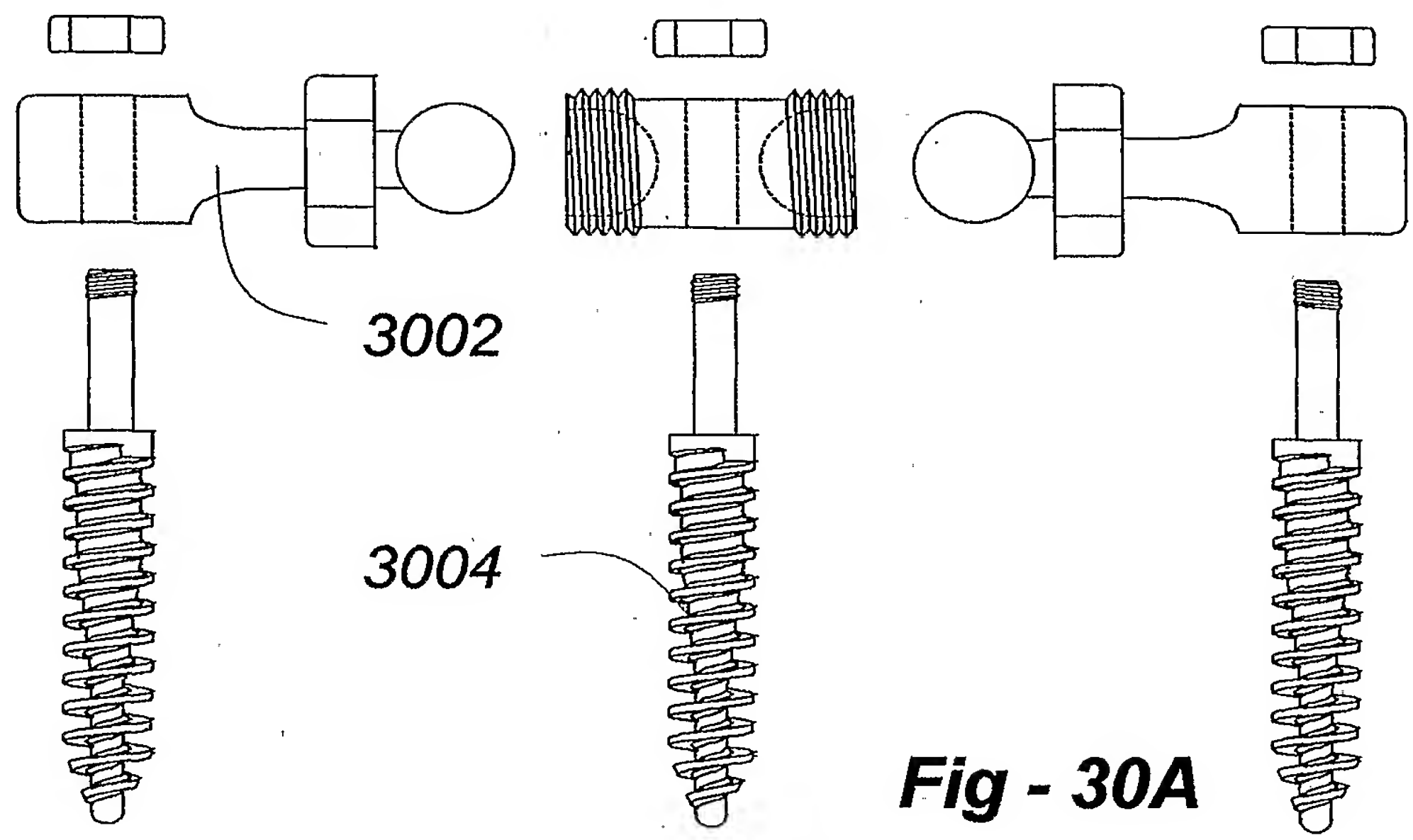


Fig - 29B



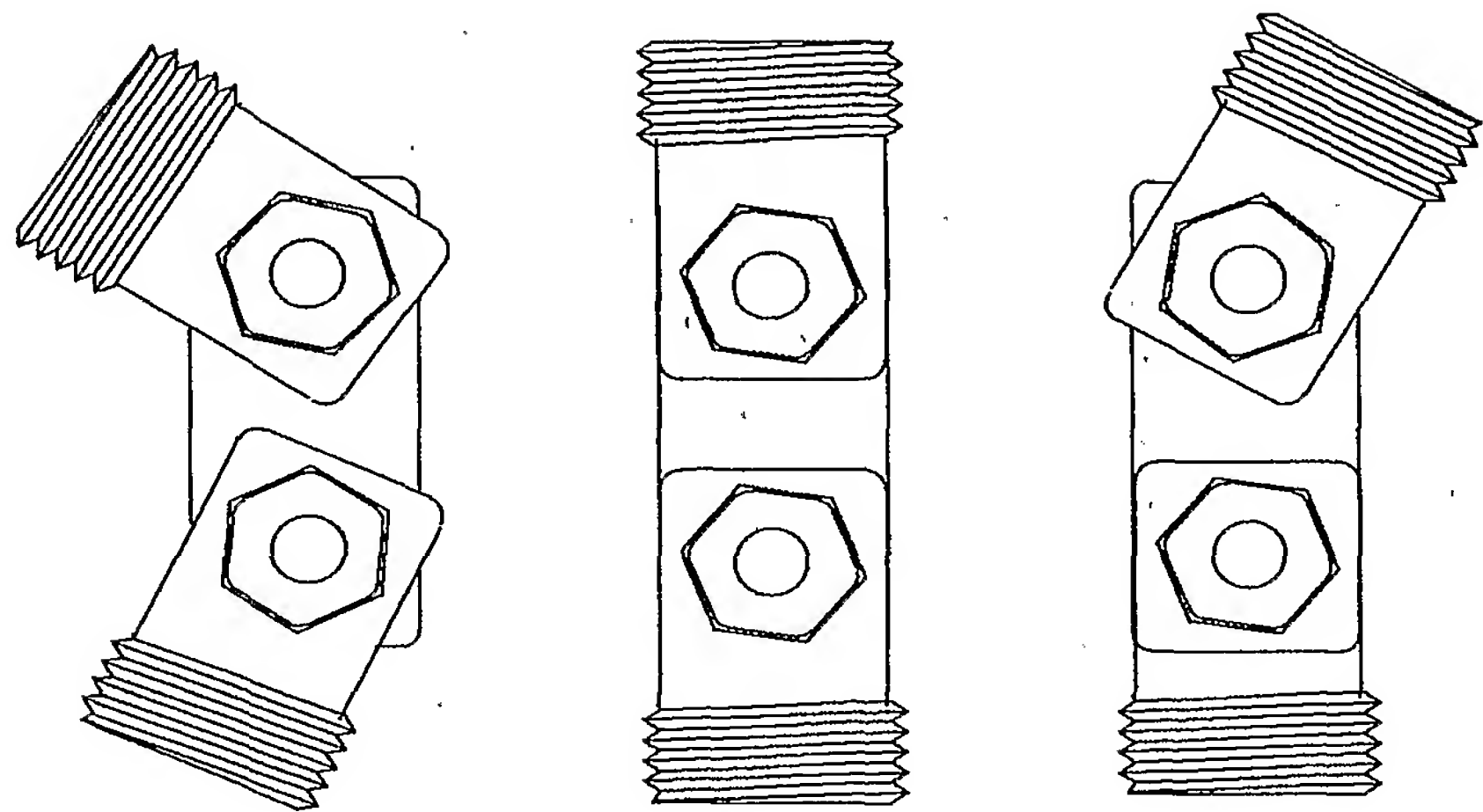


Fig - 31C

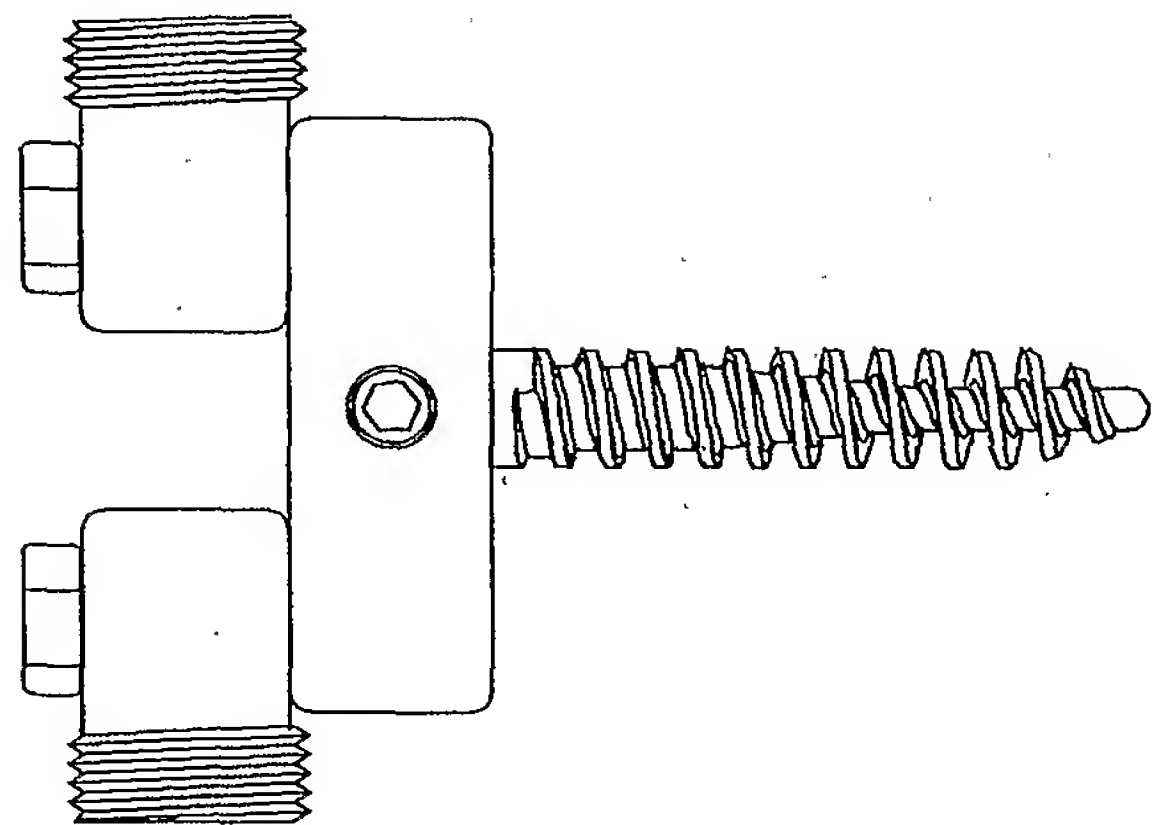


Fig - 31B

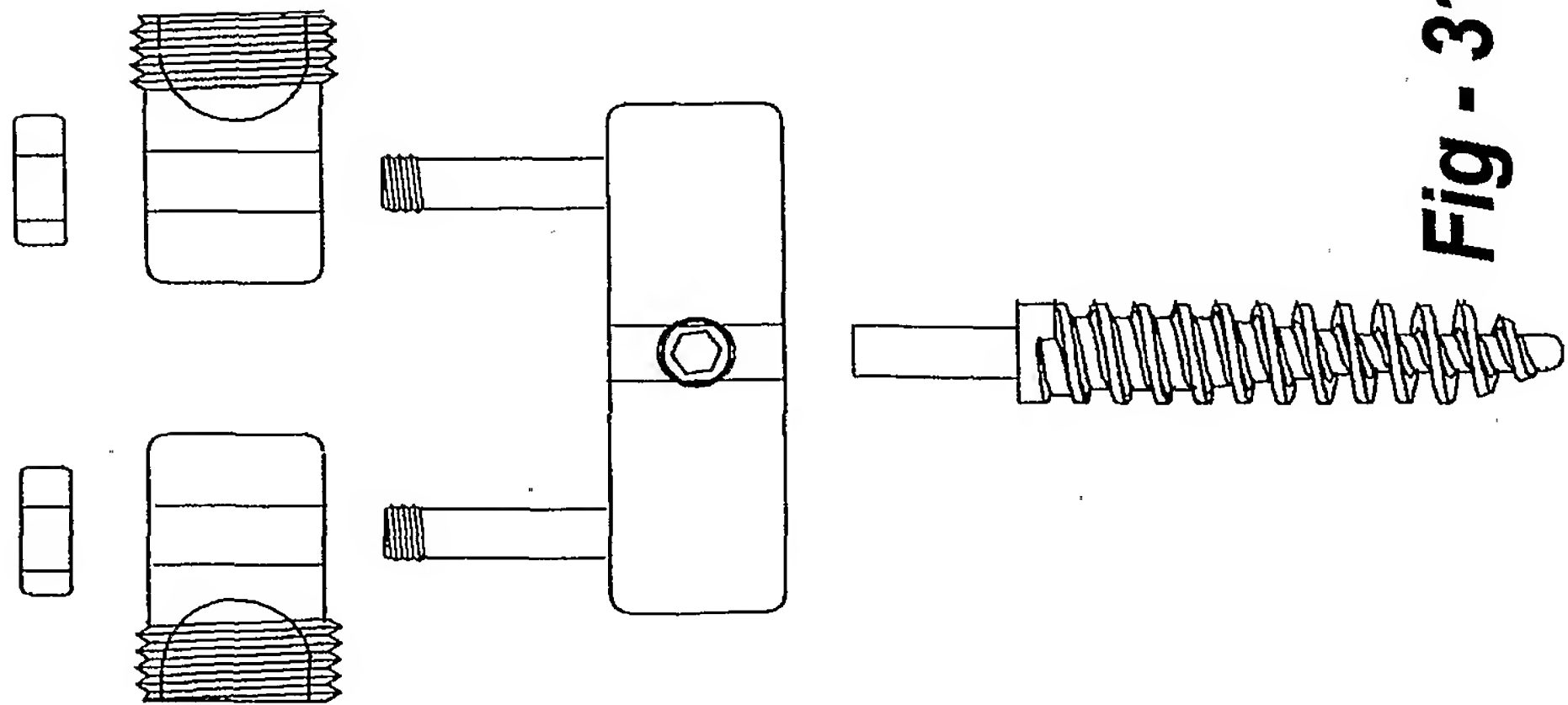


Fig - 31A

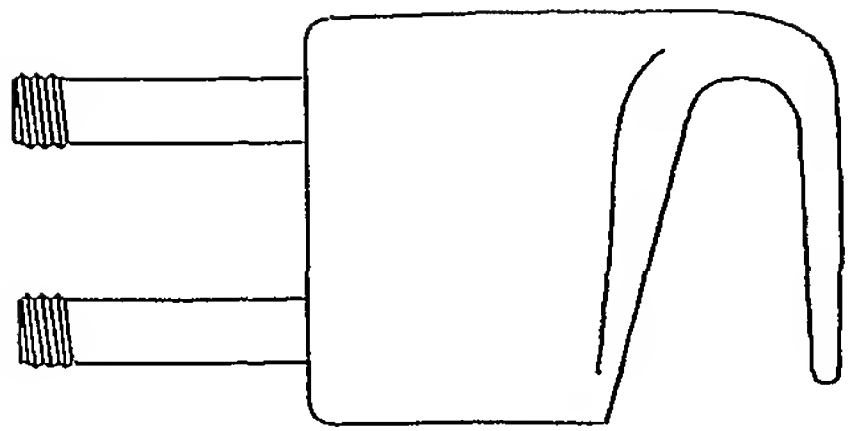


Fig - 32

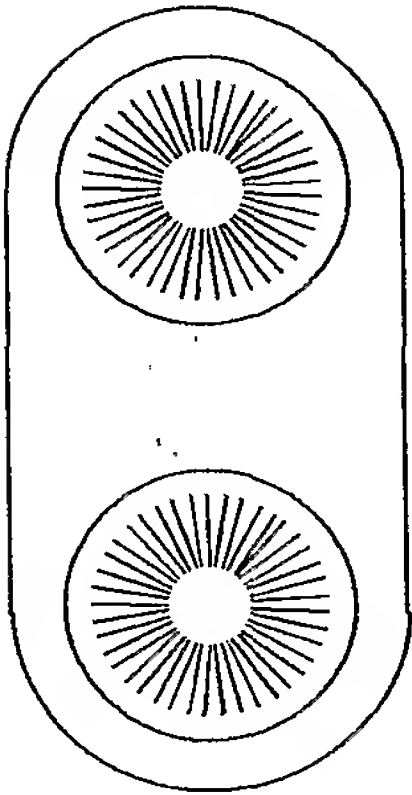


Fig - 33A

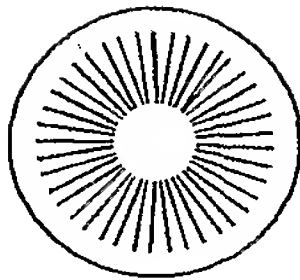


Fig - 33B

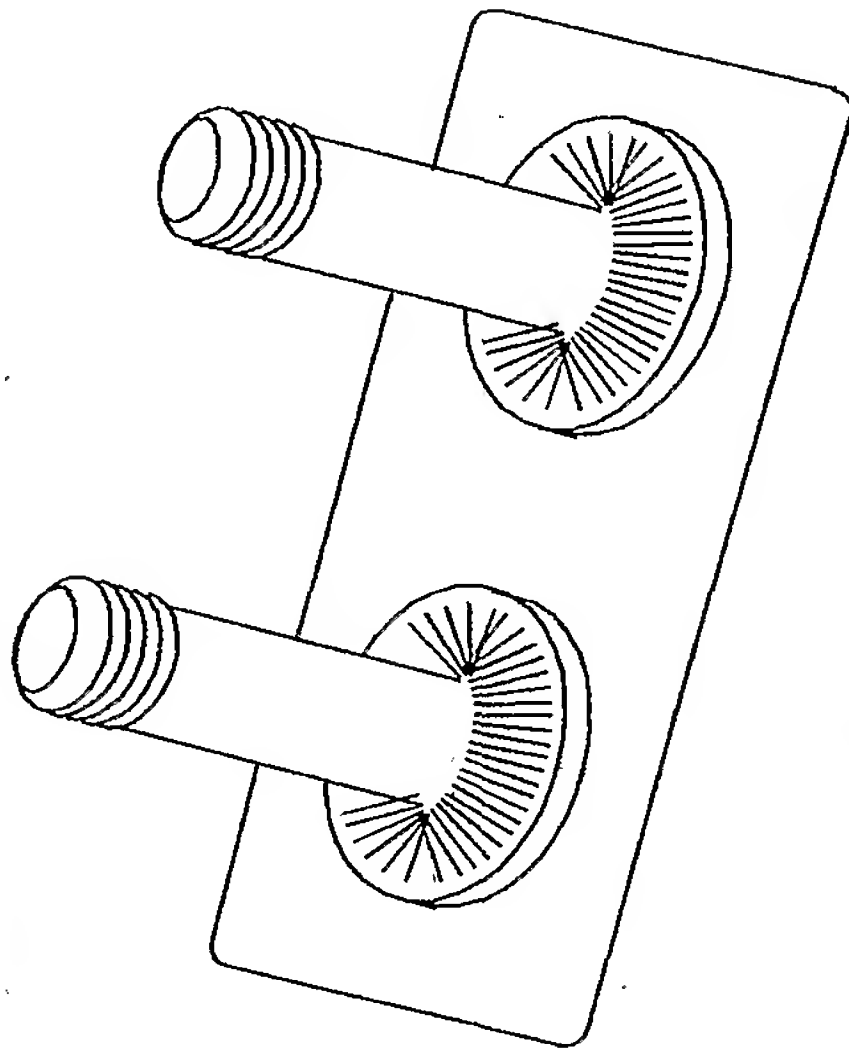
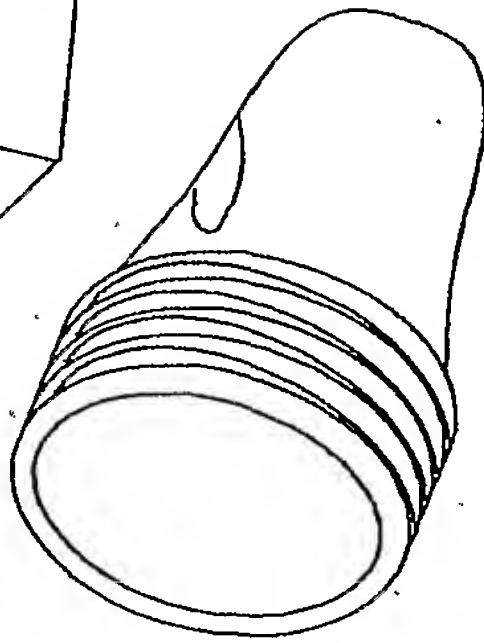
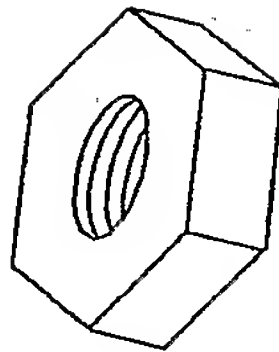


Fig - 33D

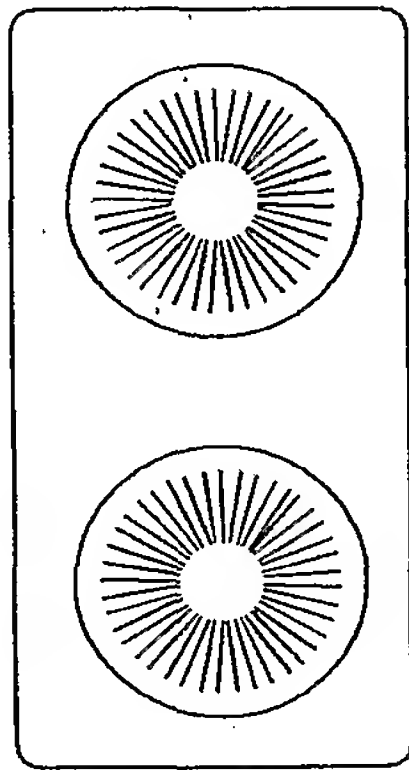


Fig - 33C

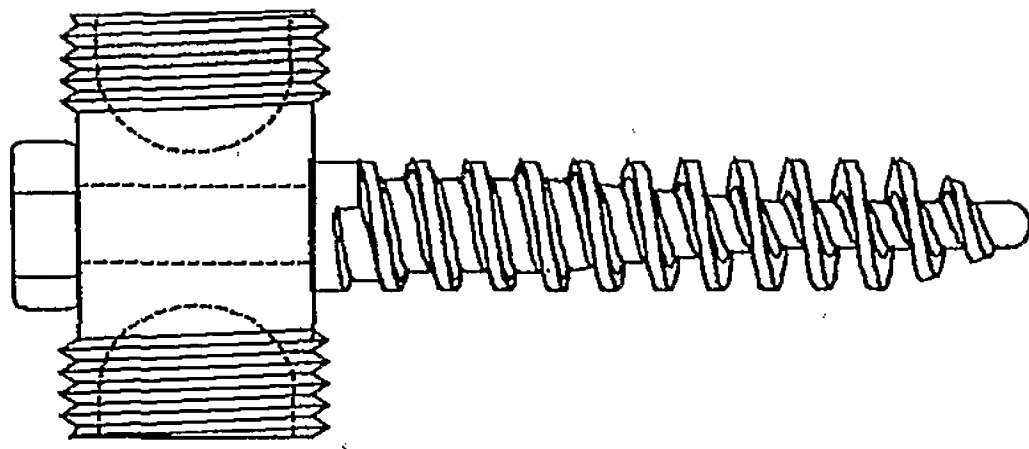
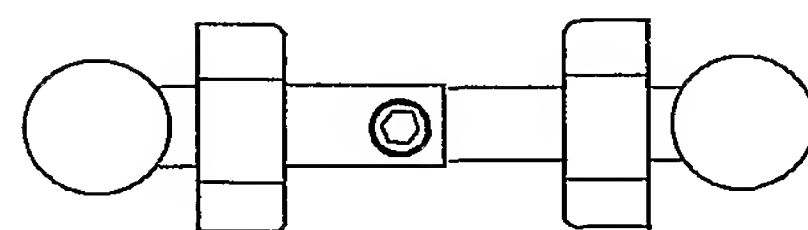
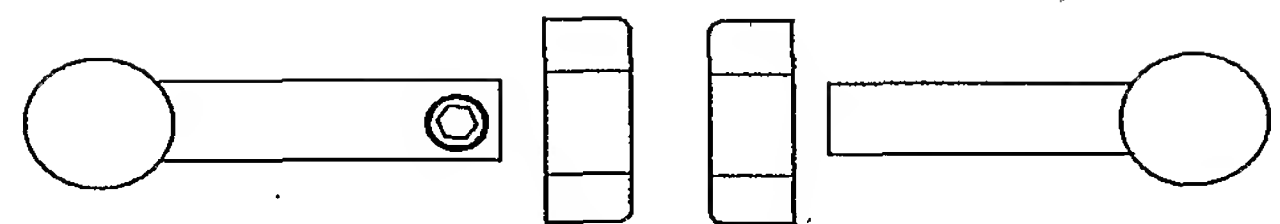
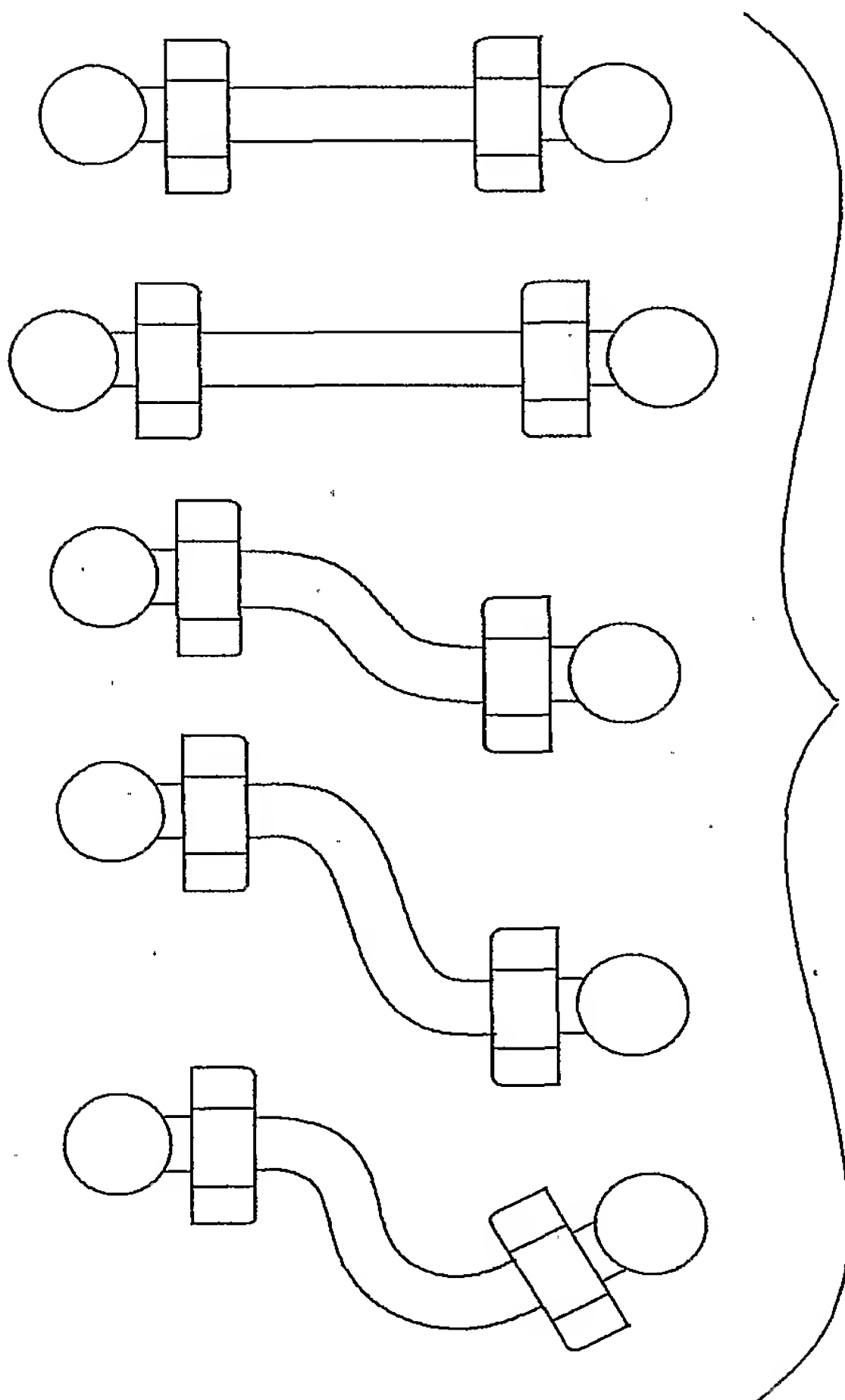
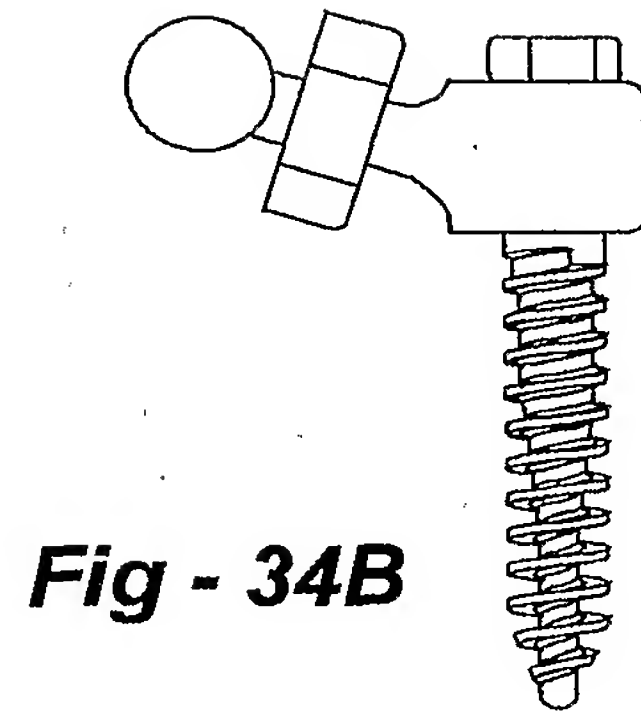
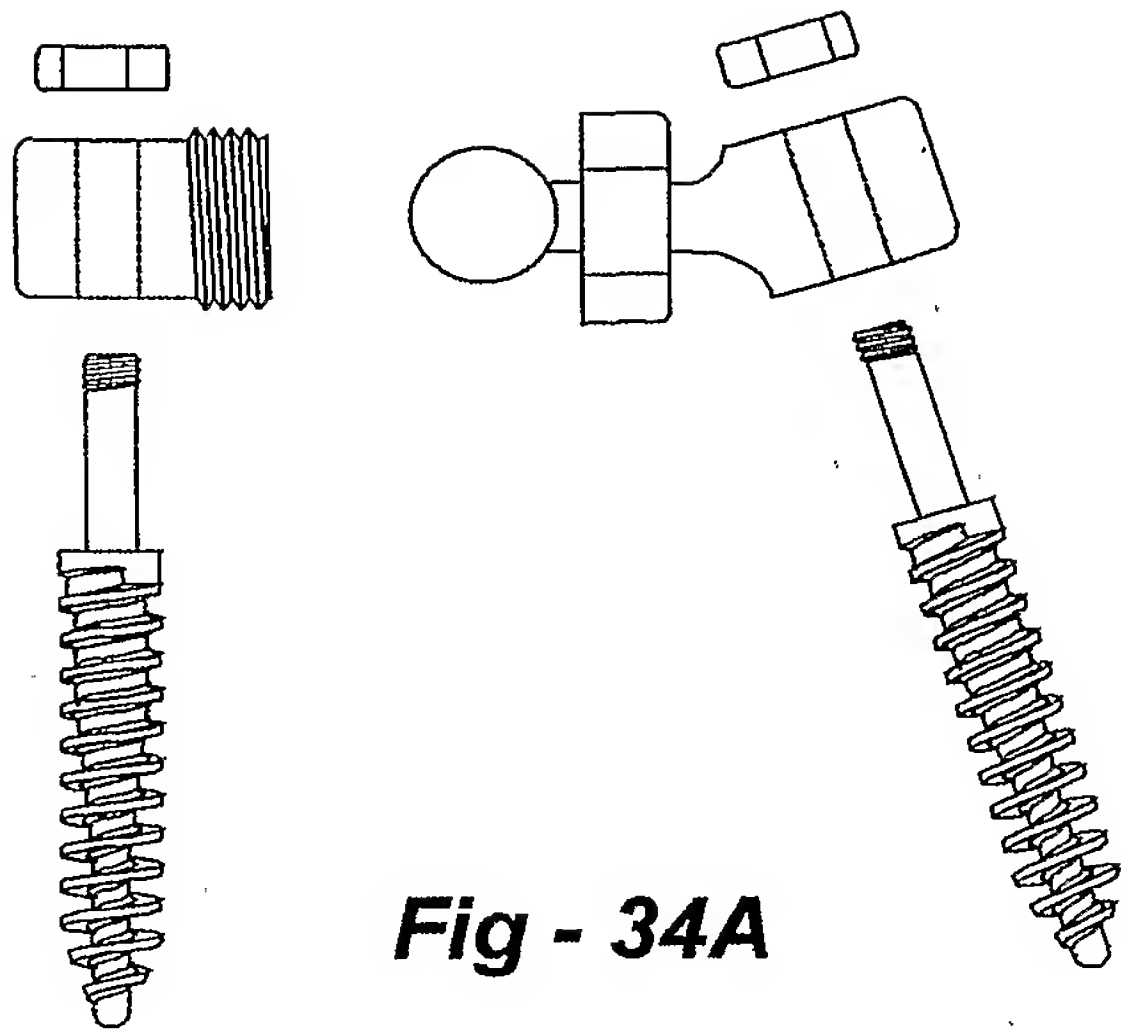


Fig - 33E



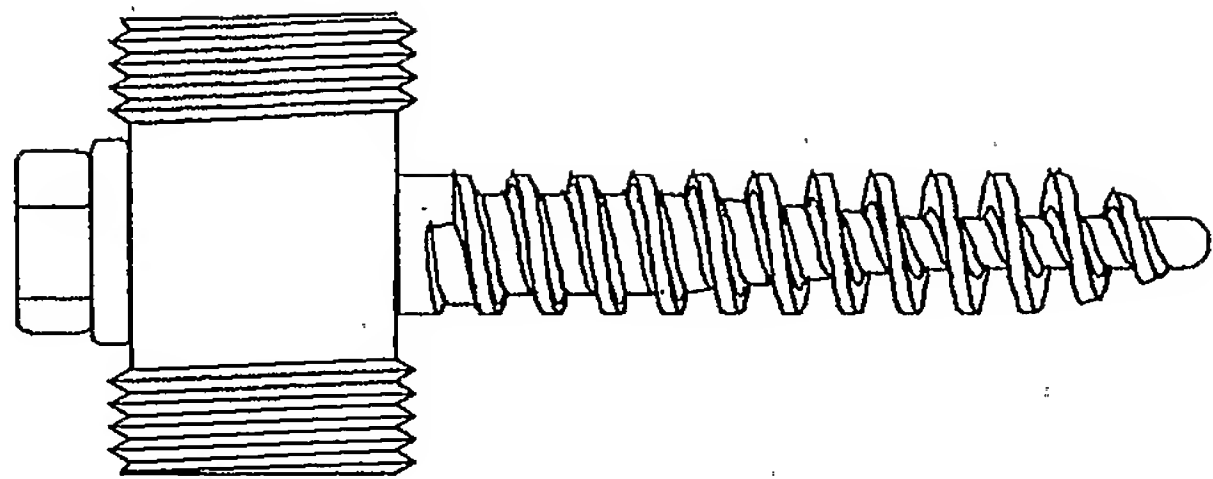


Fig - 39

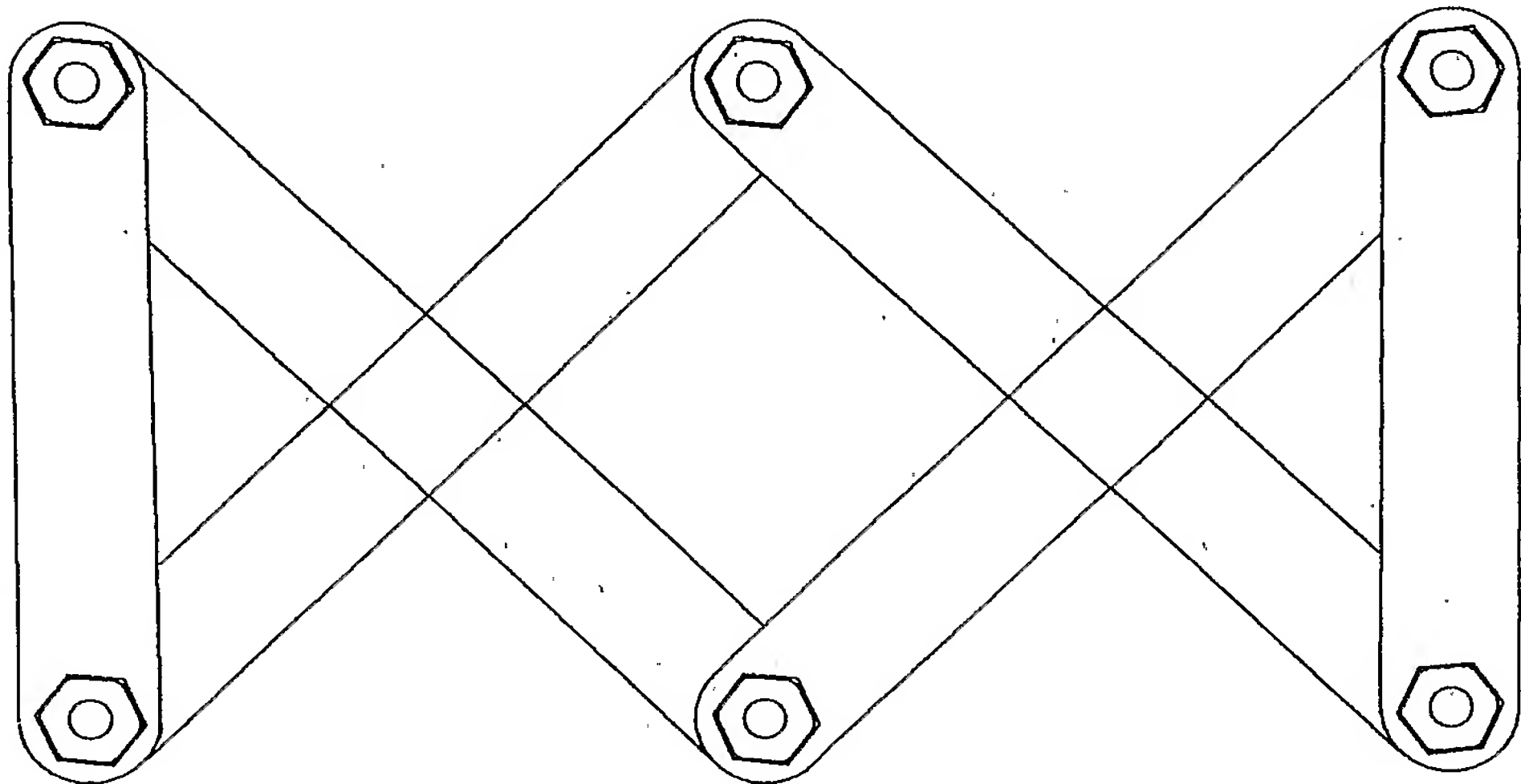


Fig - 38

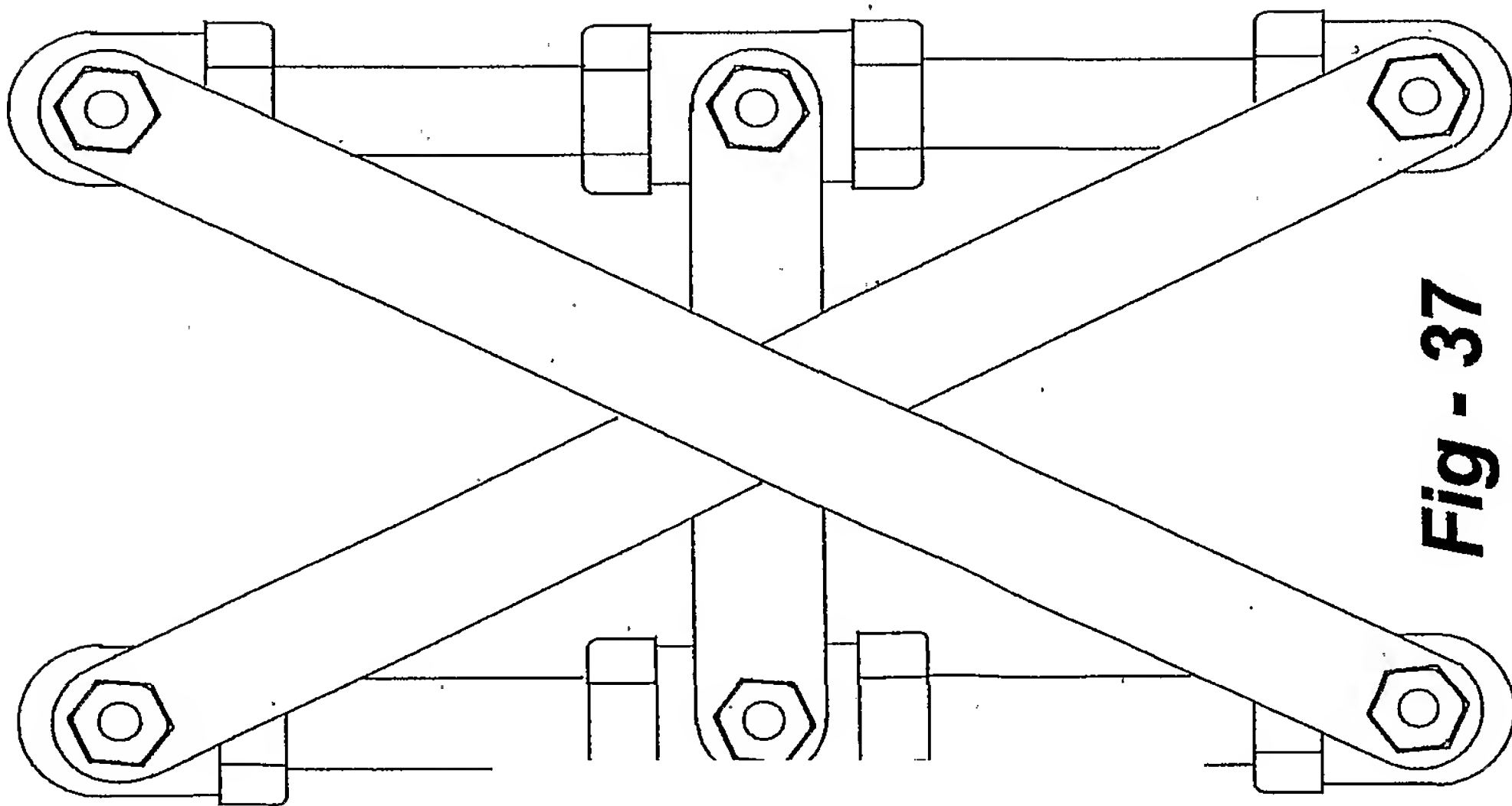


Fig - 37

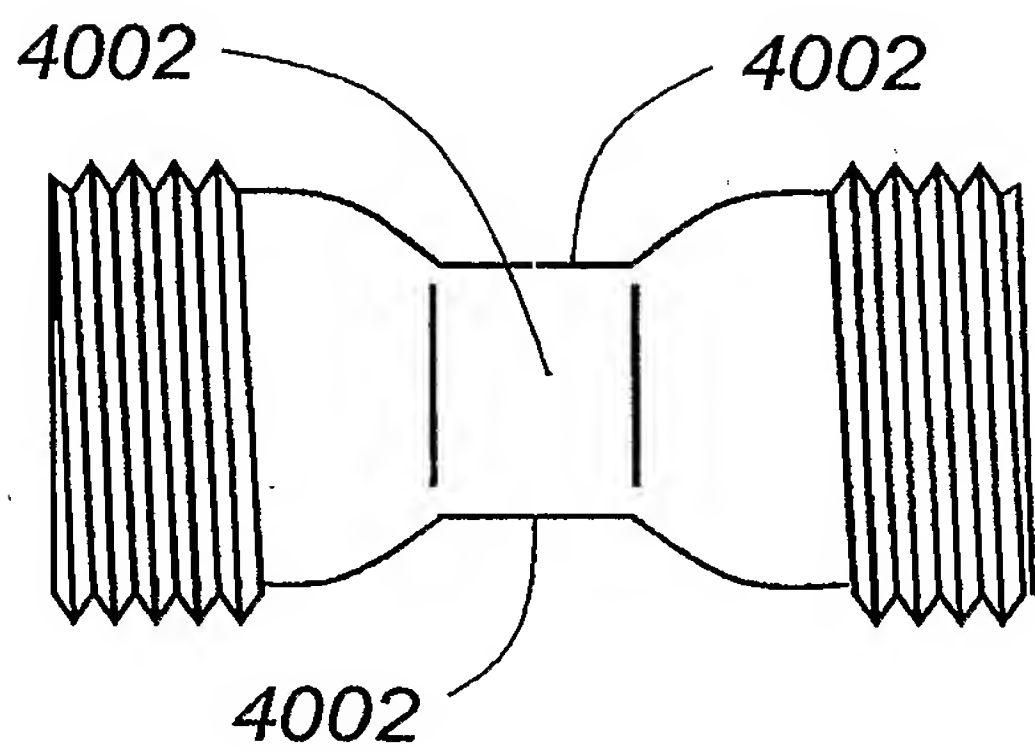


Fig - 40A

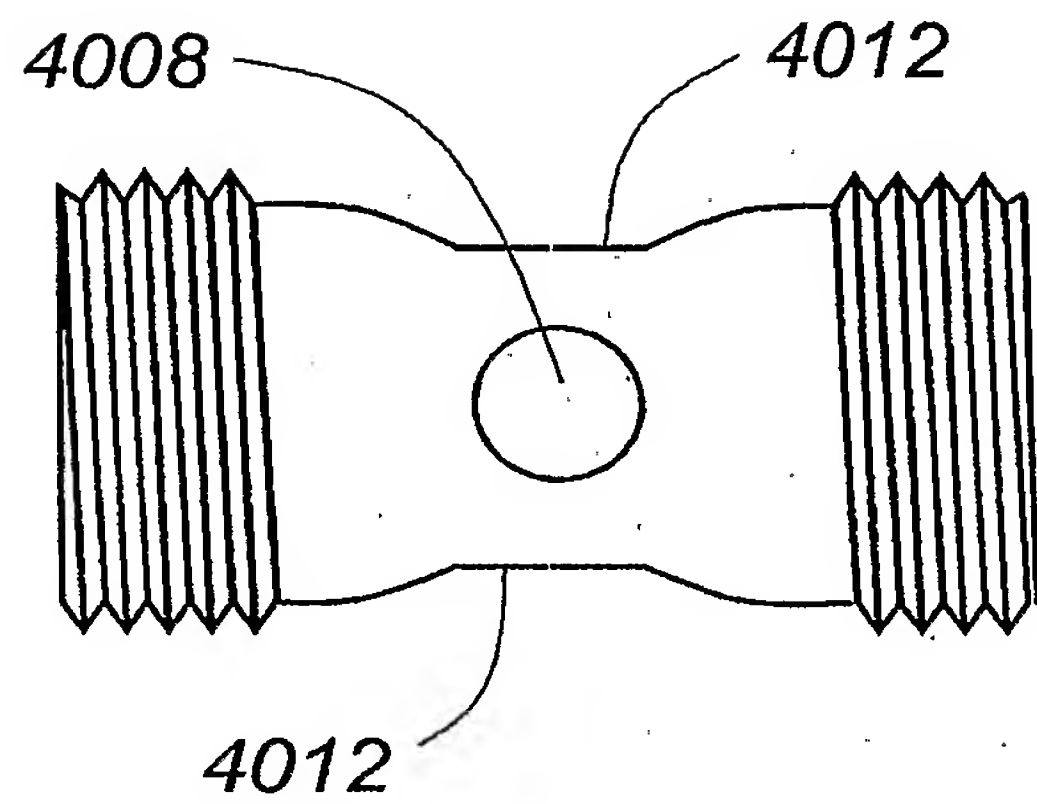


Fig - 40B

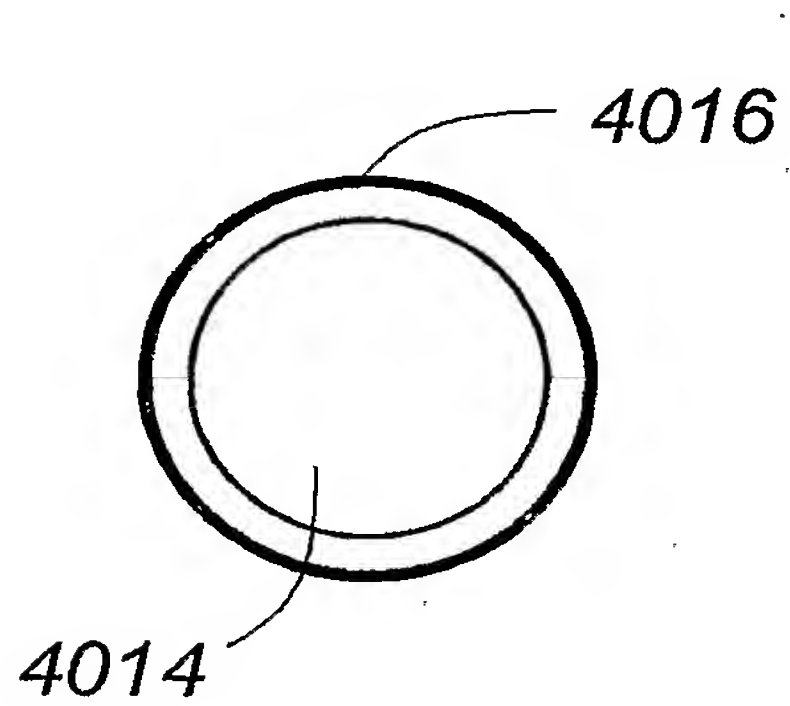


Fig - 40C

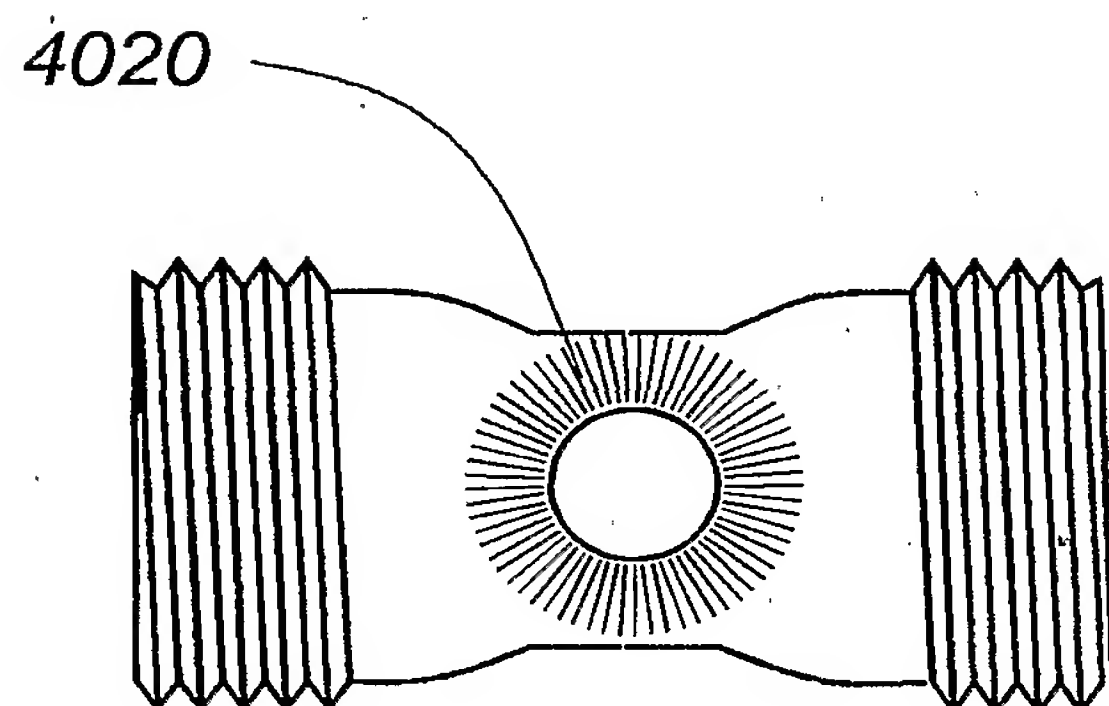


Fig - 40D

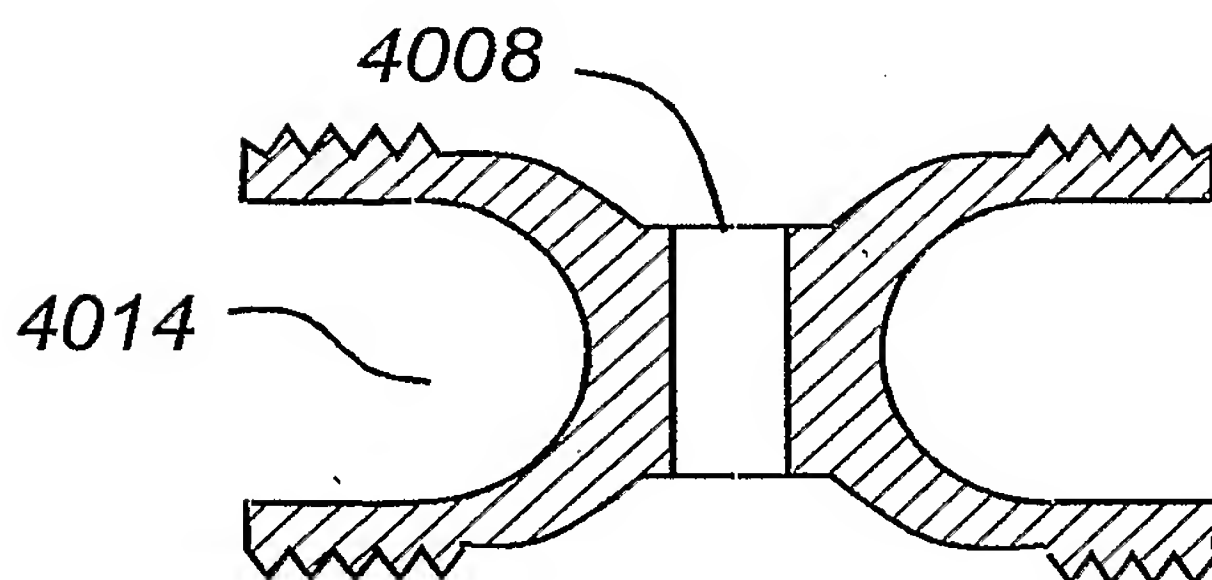


Fig - 40E

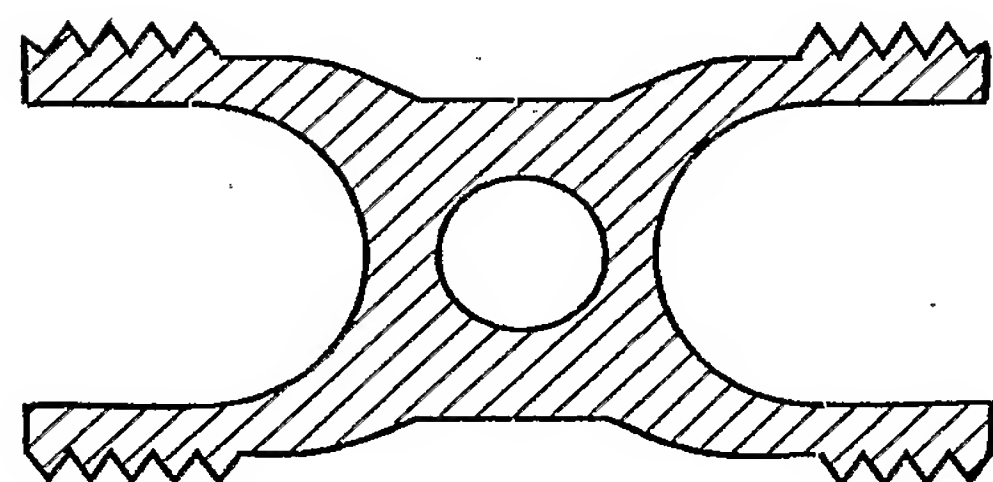


Fig - 40F

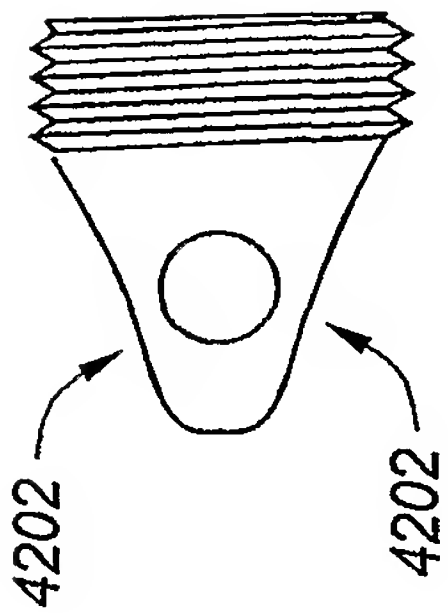


Fig - 42B

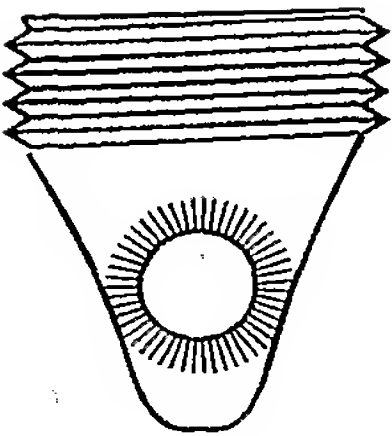


Fig - 42D

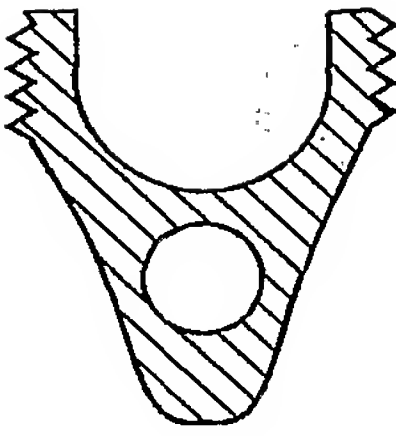


Fig - 42E

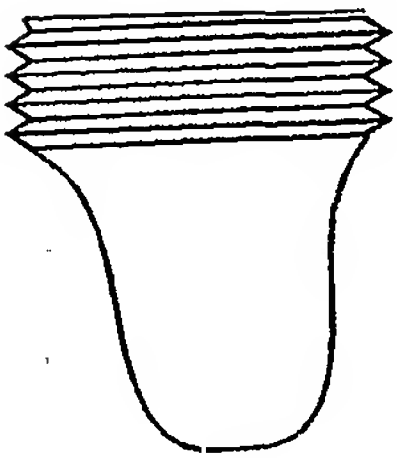


Fig - 42A

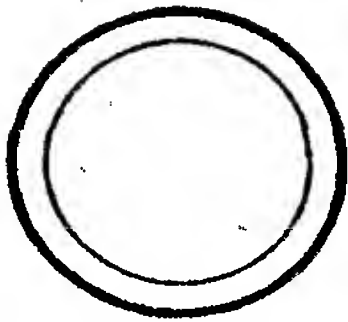


Fig - 42C

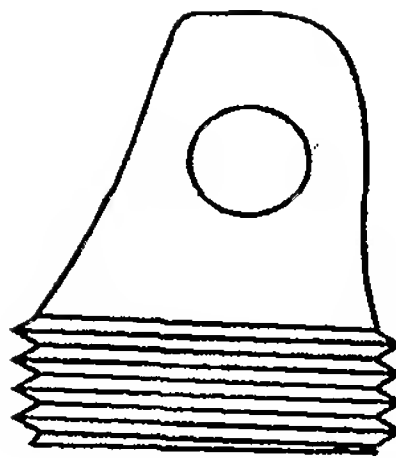


Fig - 41G

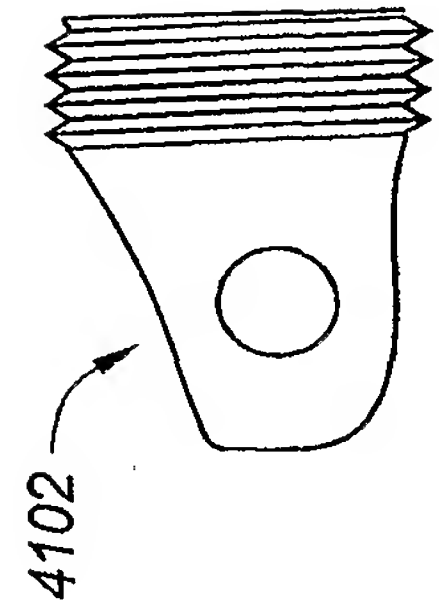


Fig - 41B

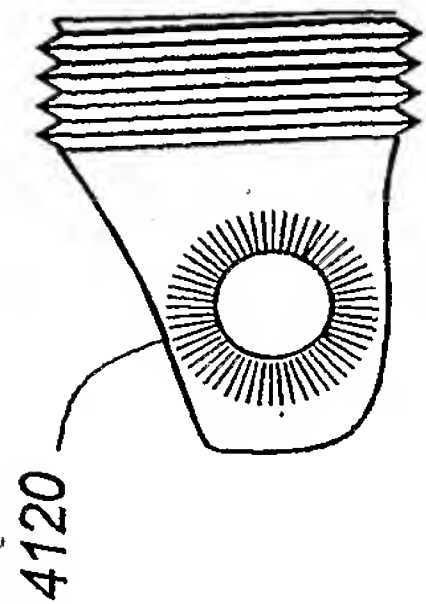


Fig - 41D

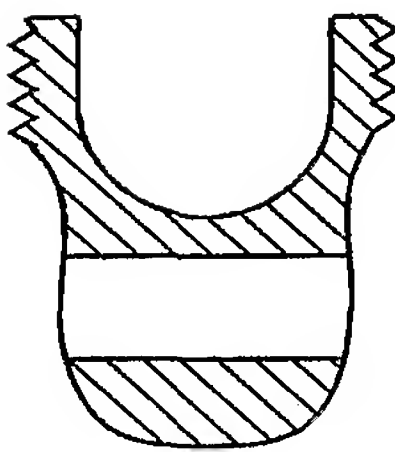


Fig - 41F

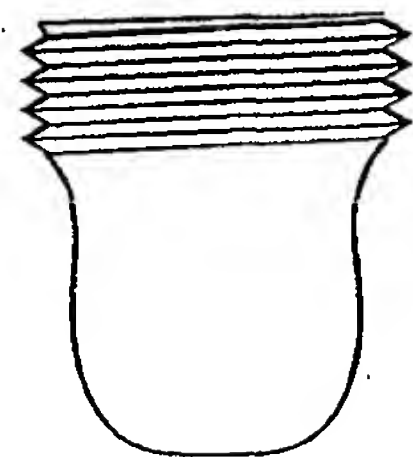


Fig - 41A

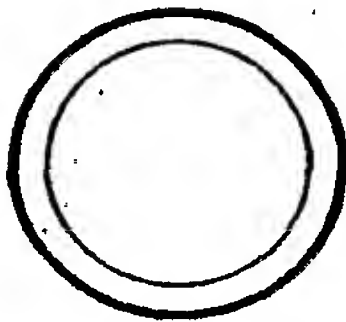


Fig - 41C

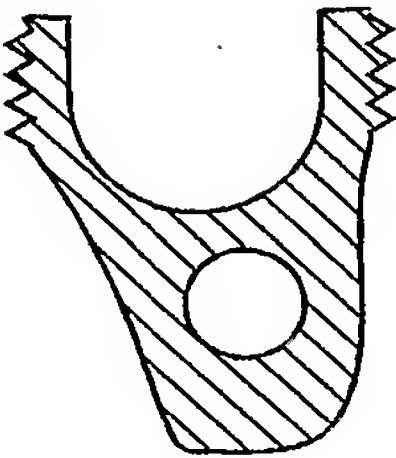


Fig - 41E

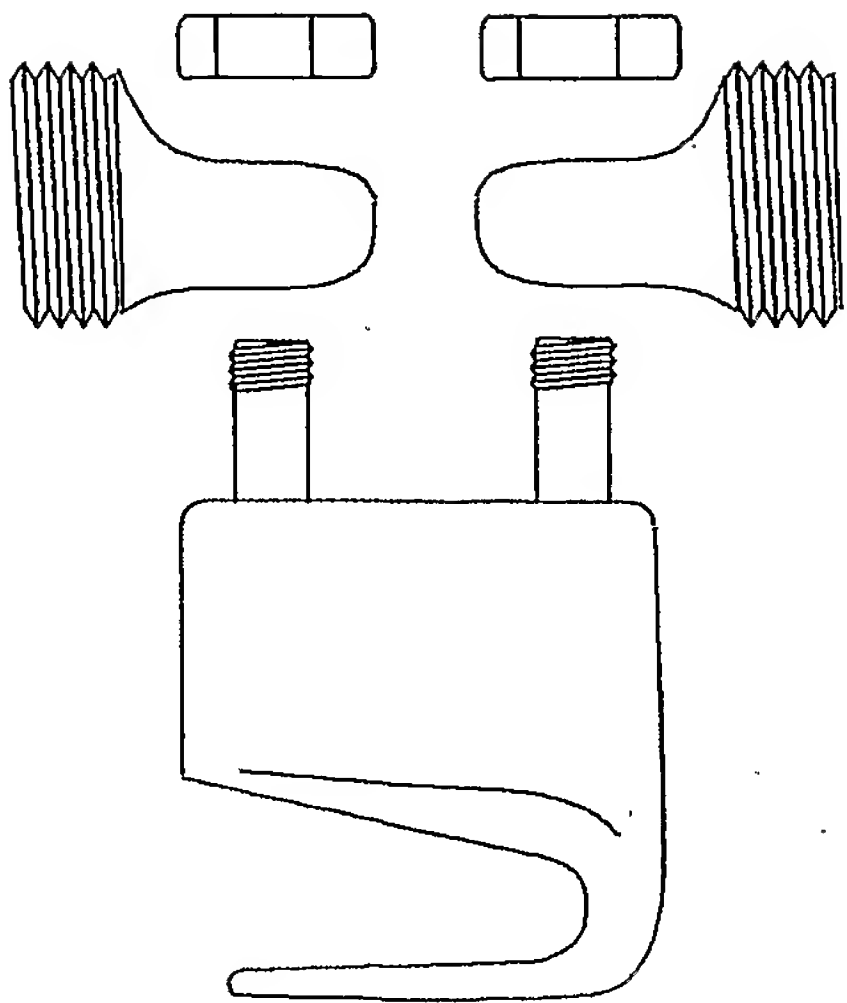


Fig - 43A

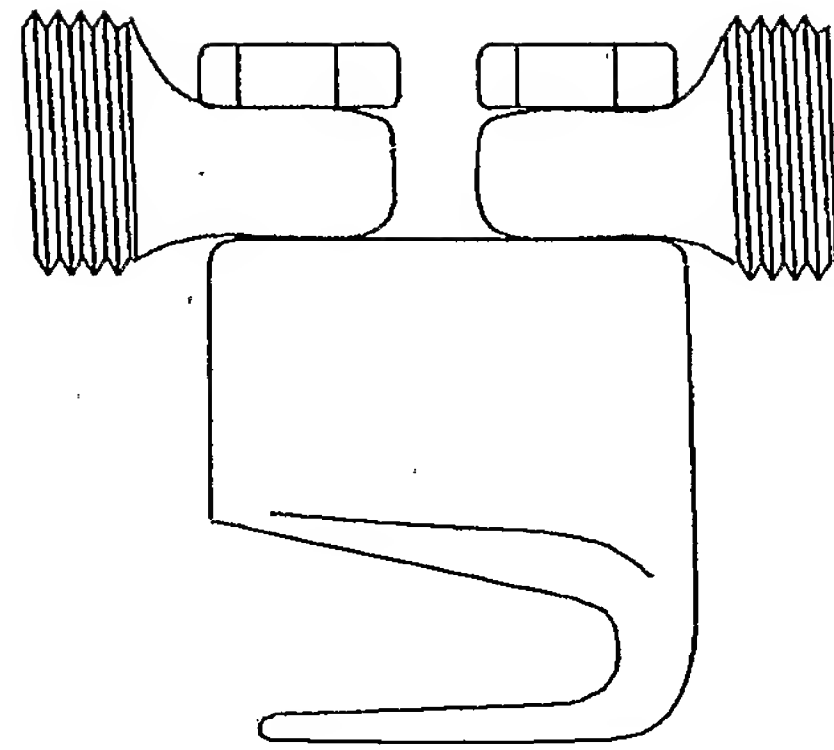


Fig - 43B

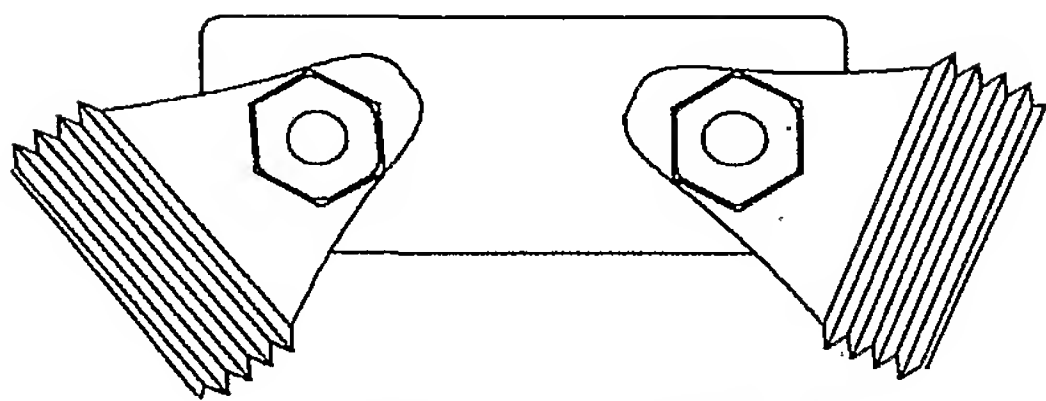


Fig - 44A

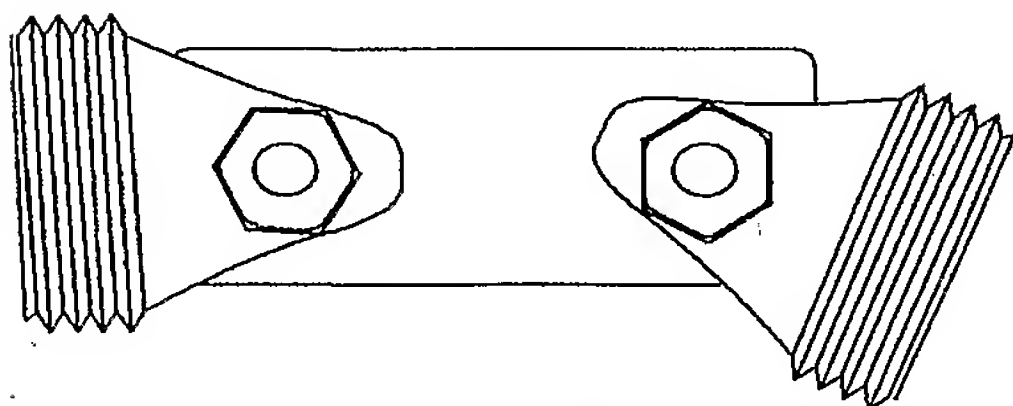


Fig - 44B

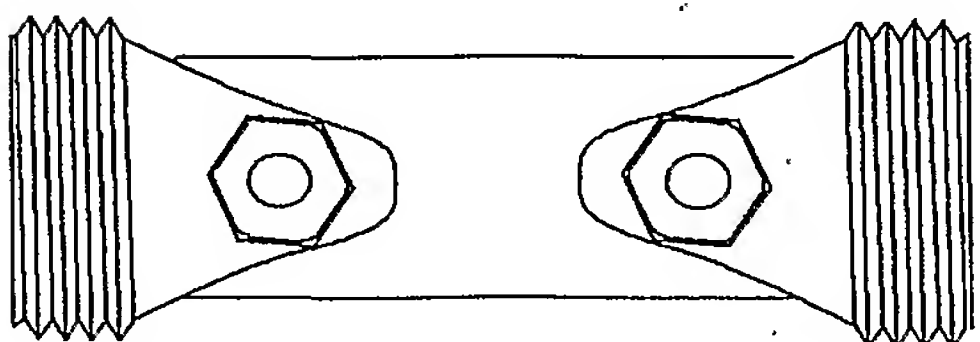


Fig - 44C

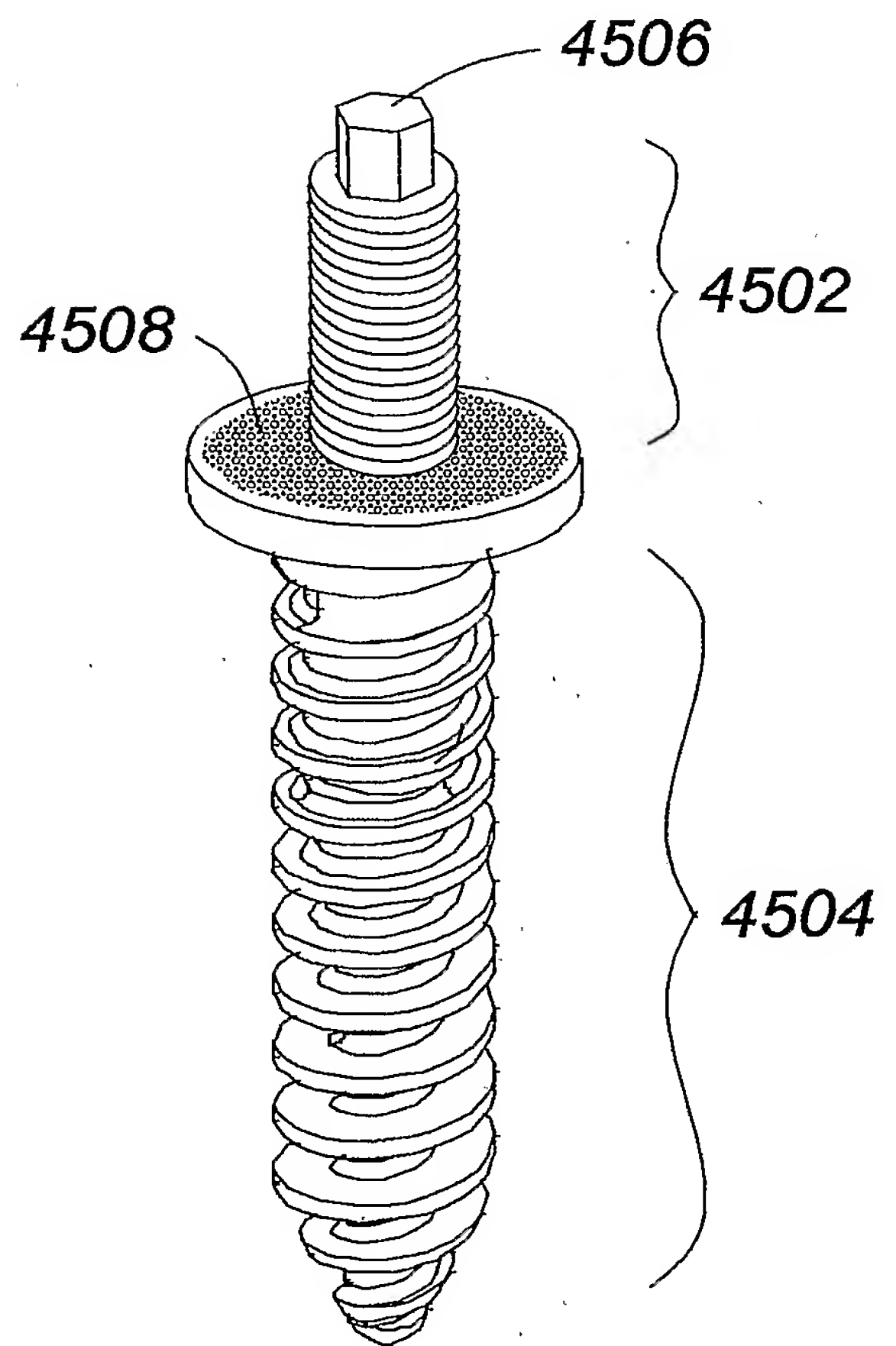


Fig - 45

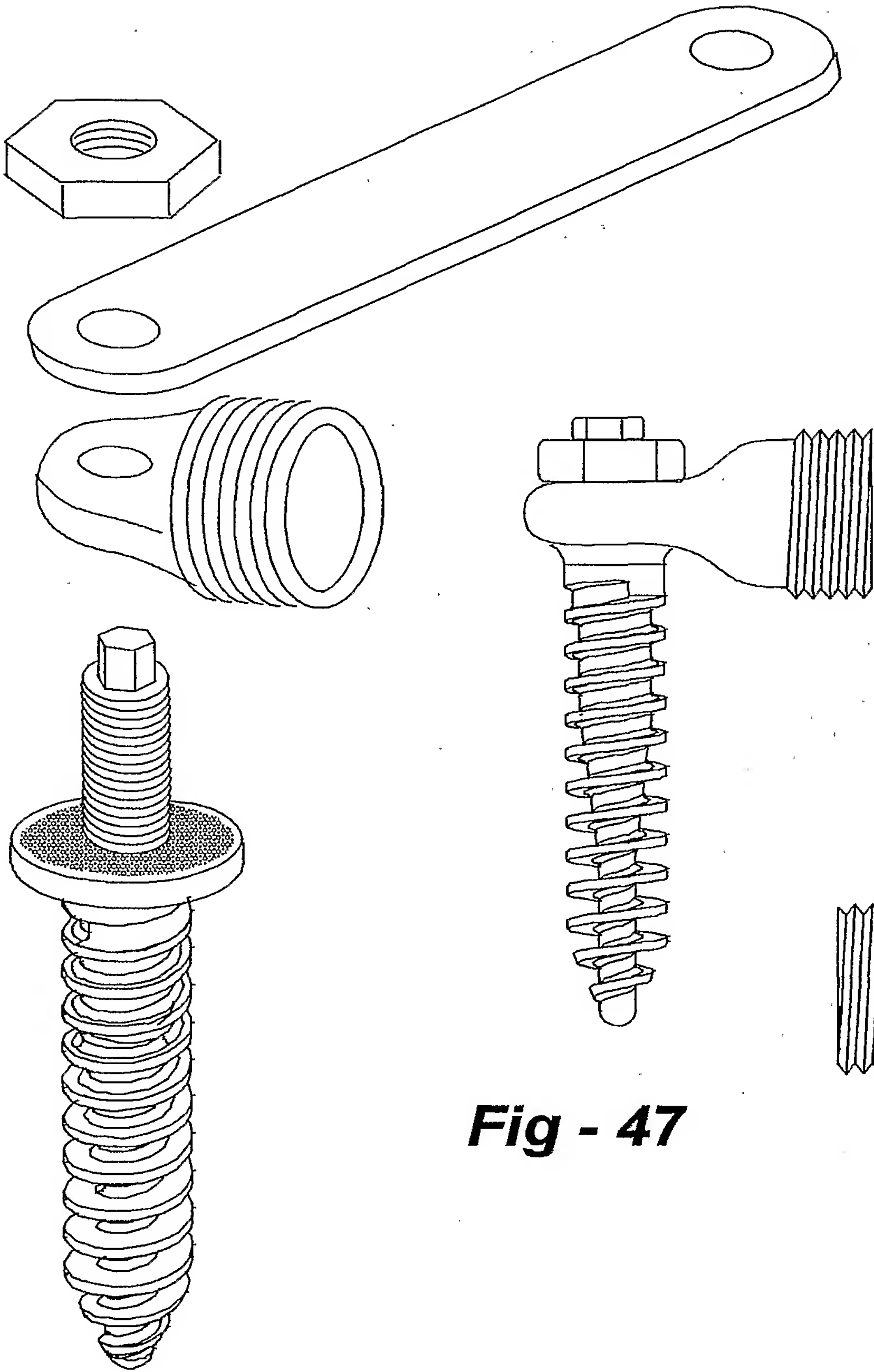


Fig - 47

Fig - 46

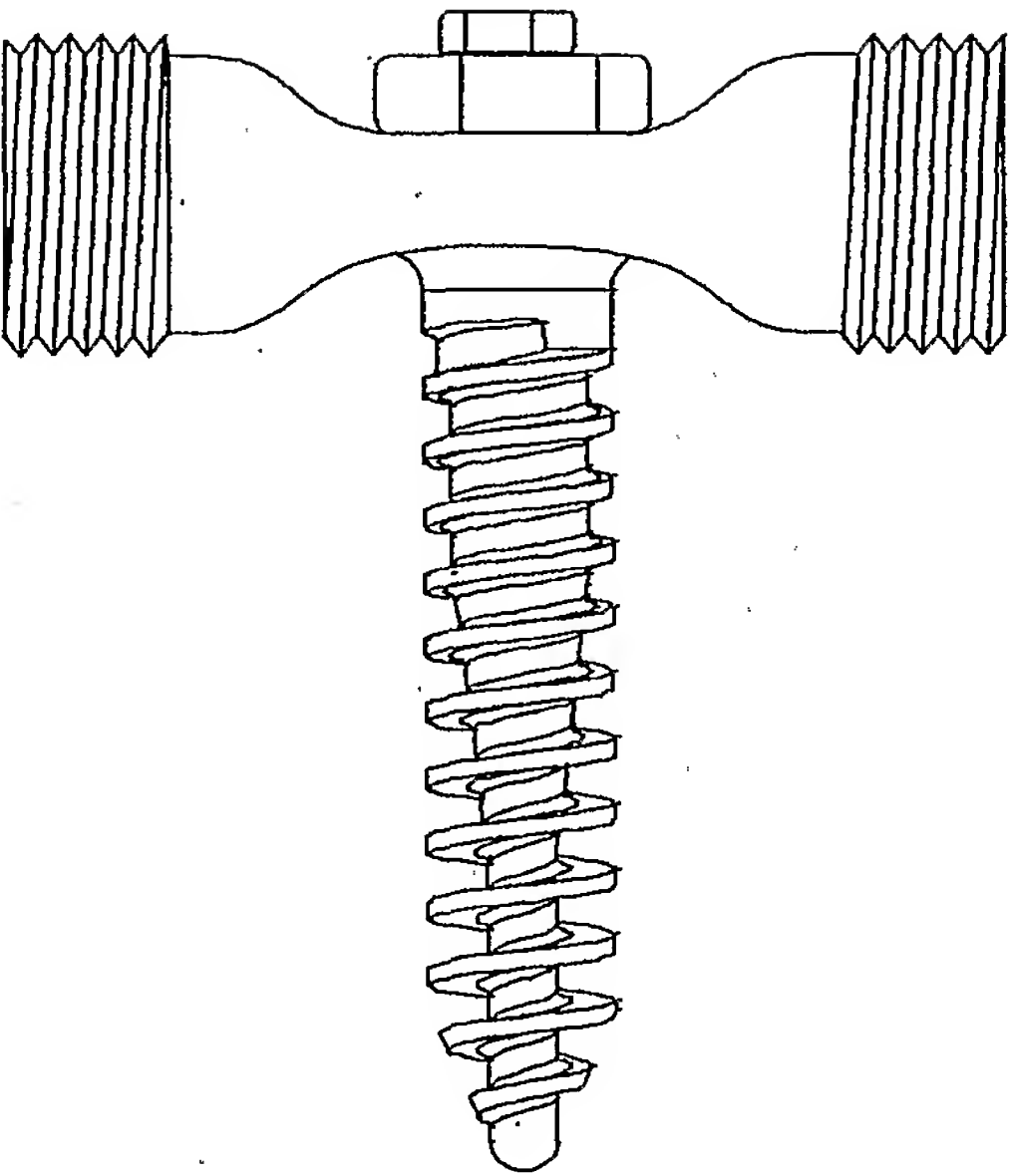


Fig - 48

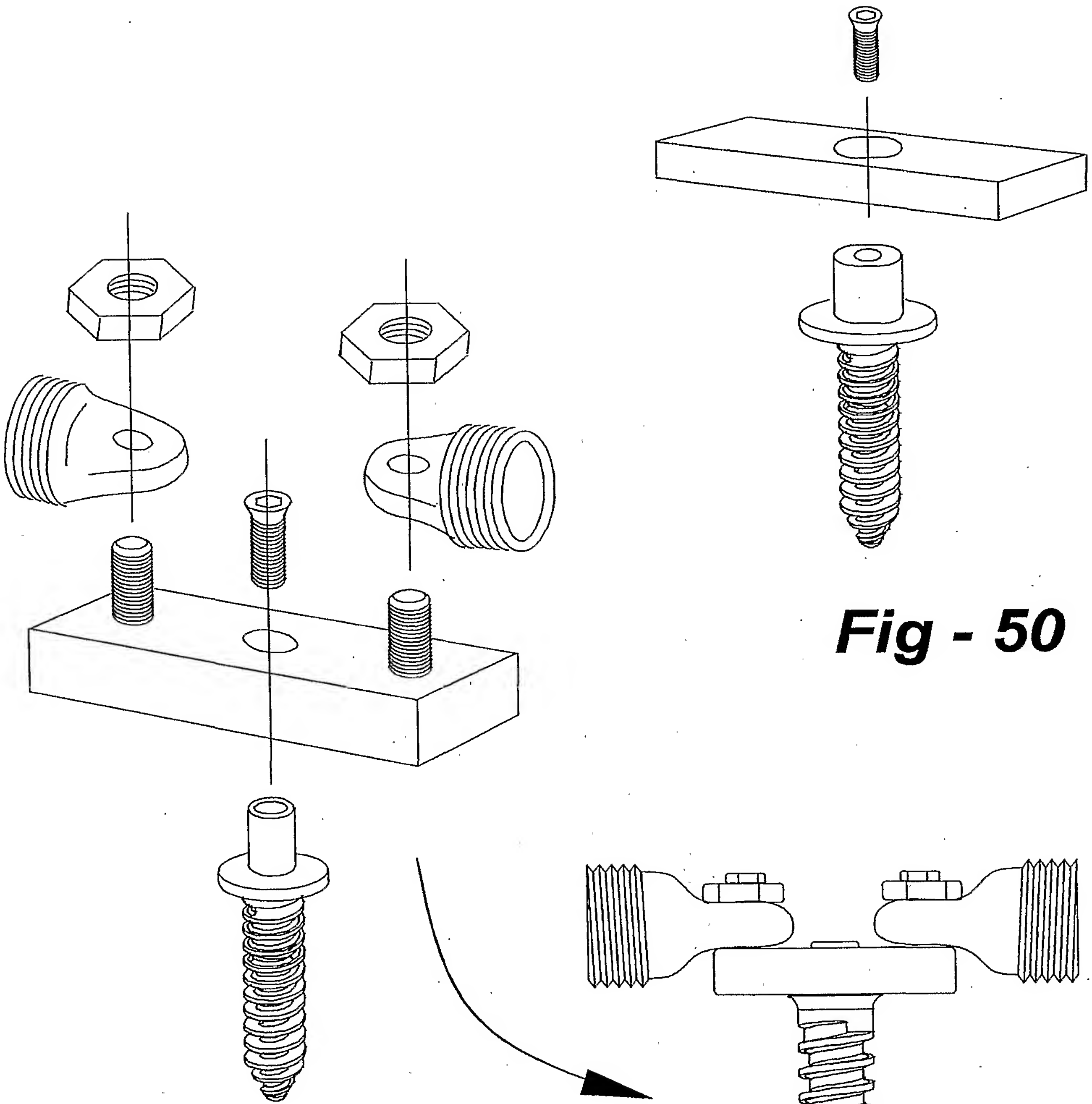


Fig - 50

Fig - 49

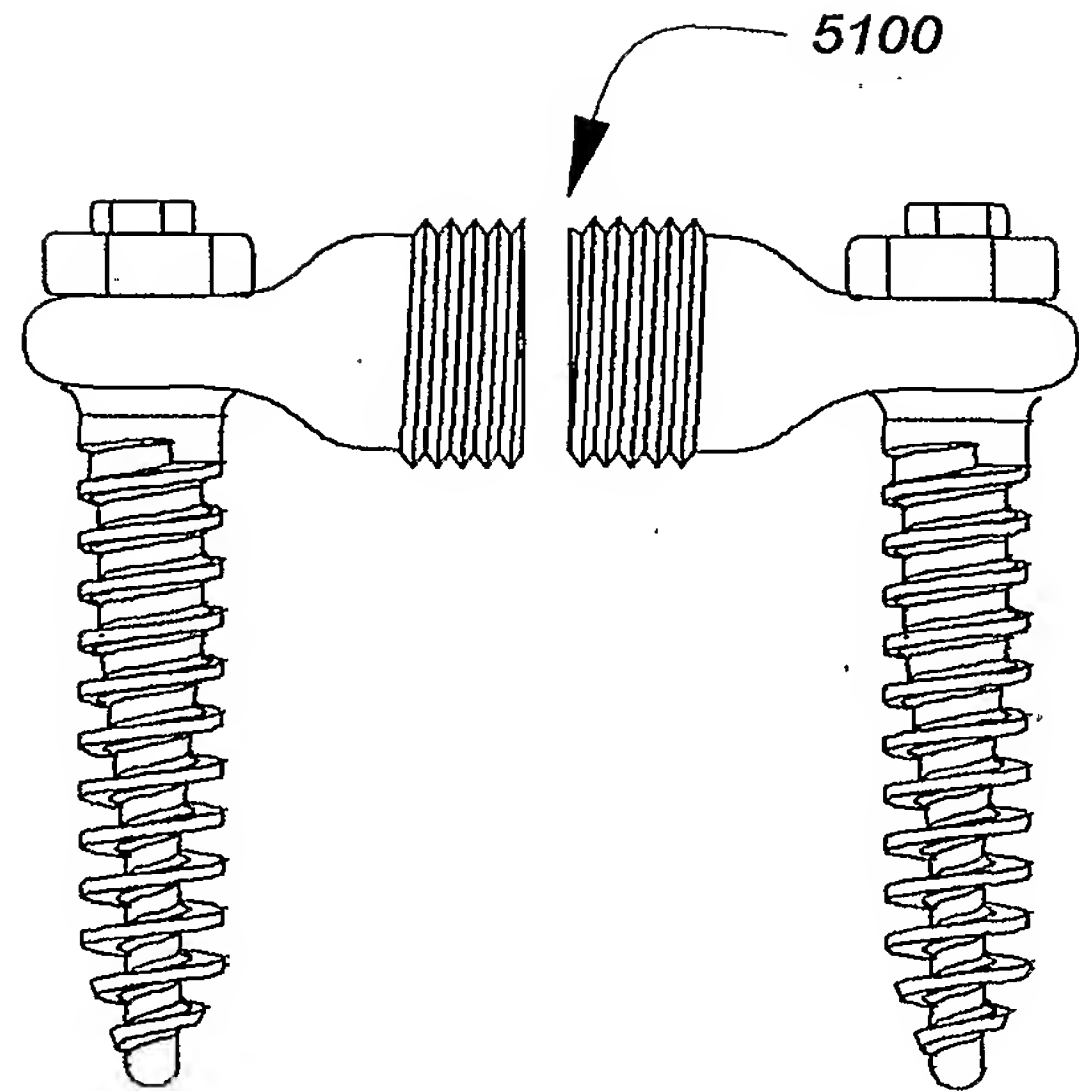
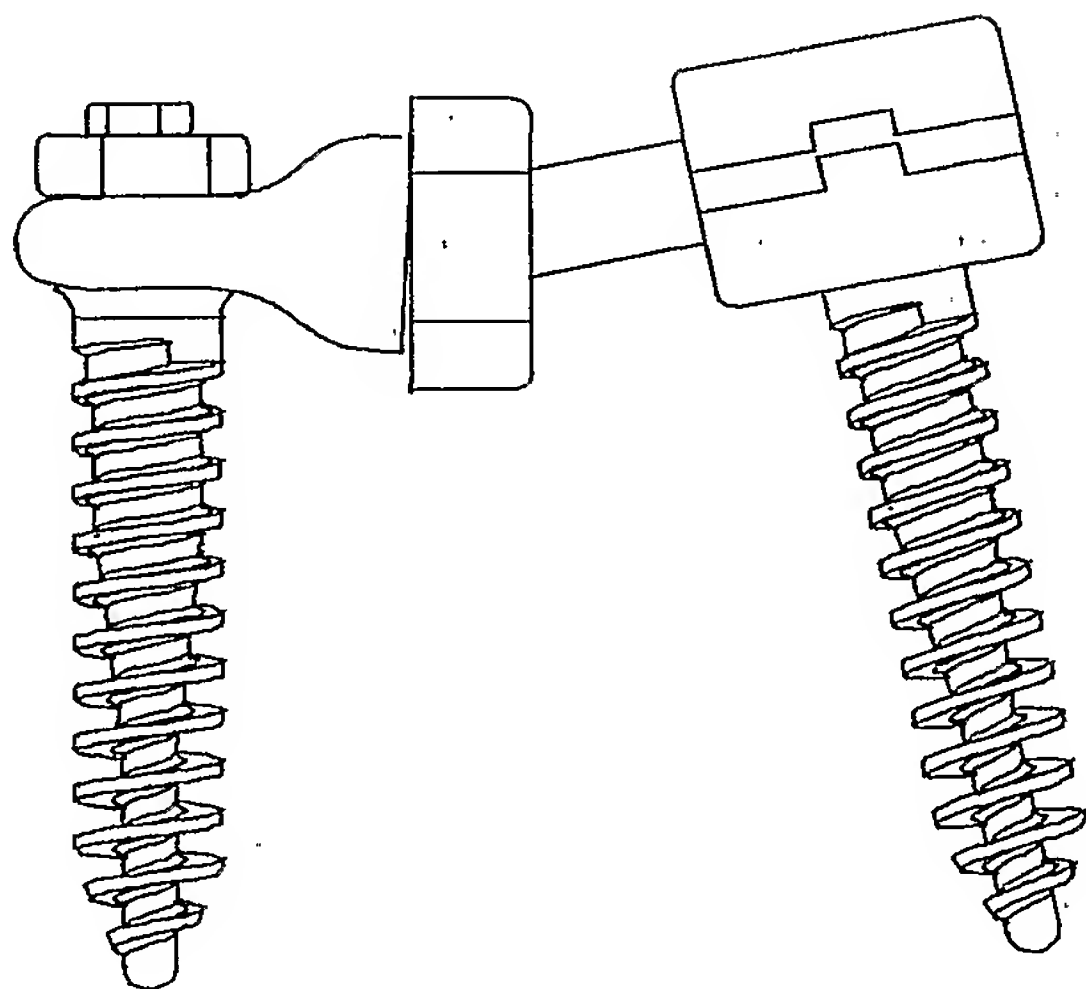
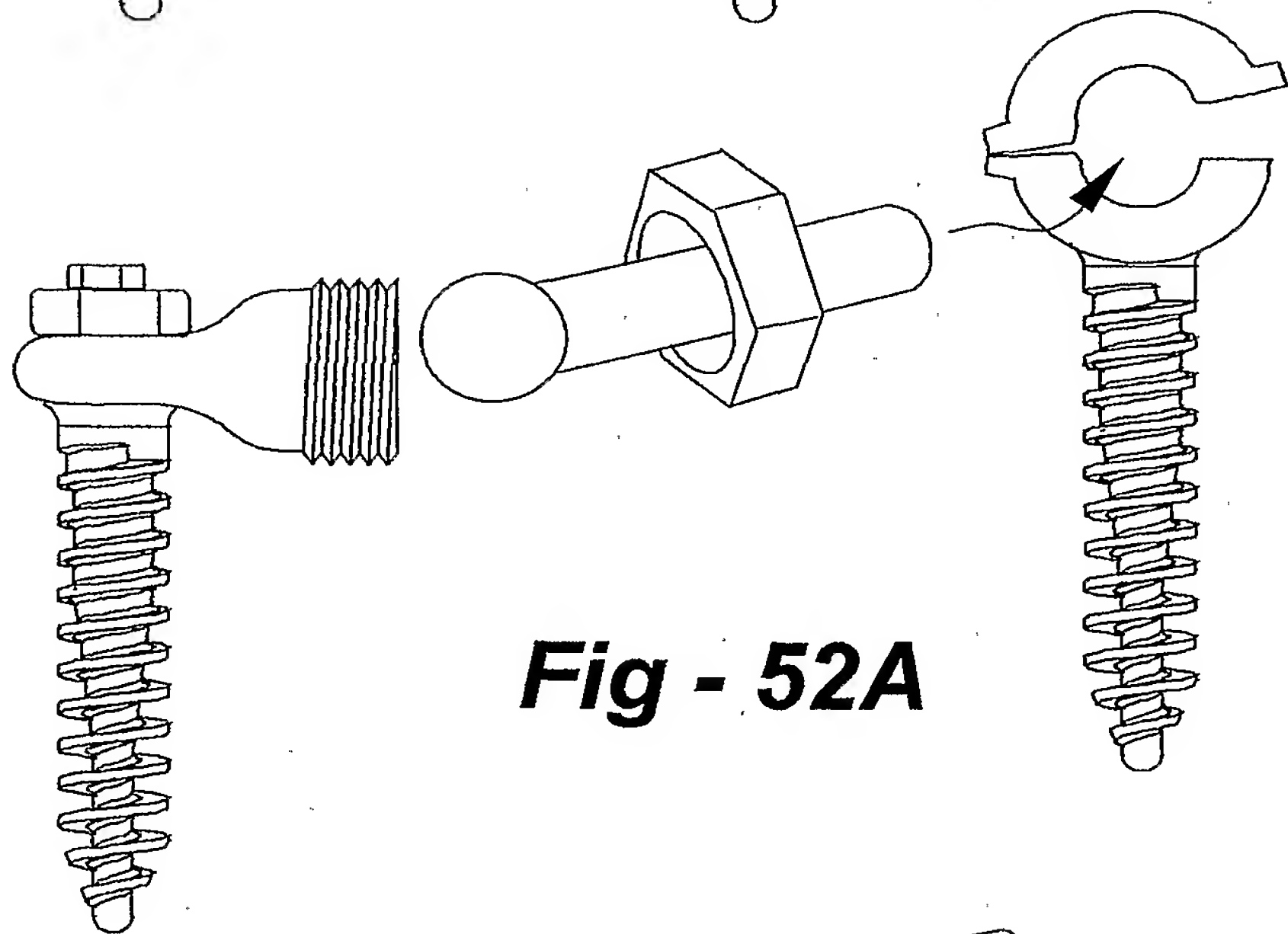


Fig - 51



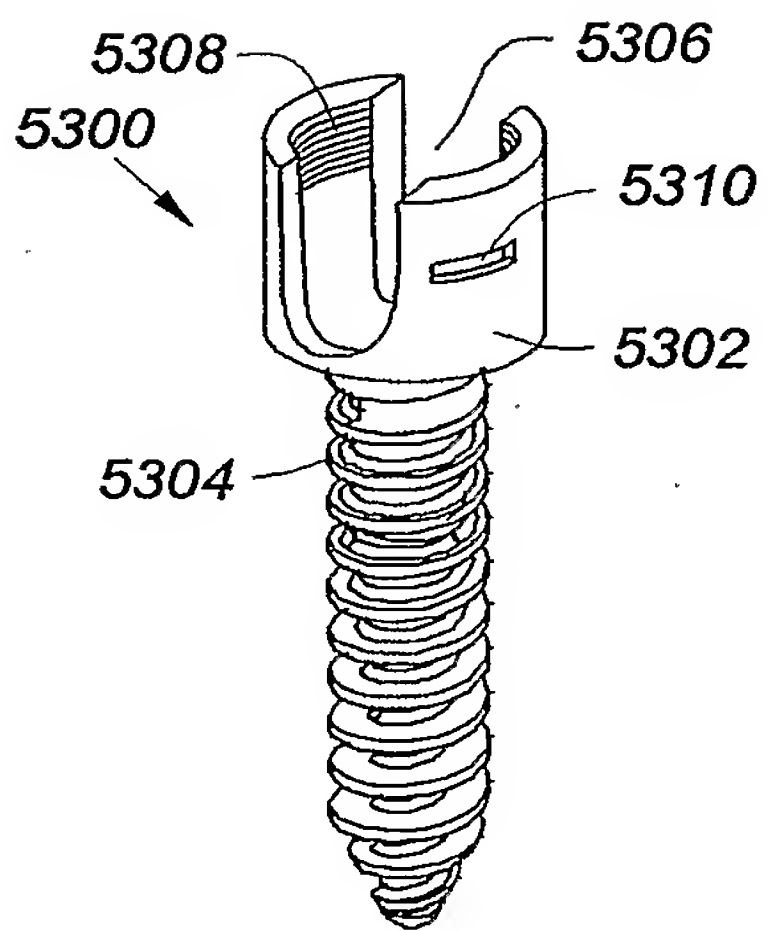


Fig - 53A

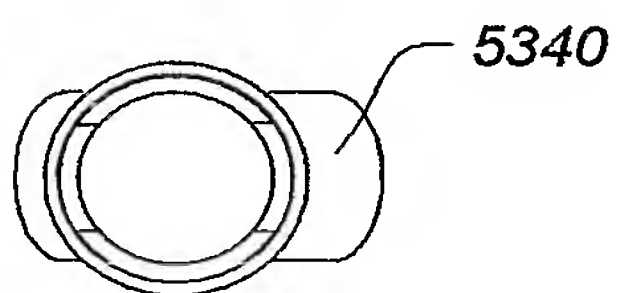


Fig - 53E

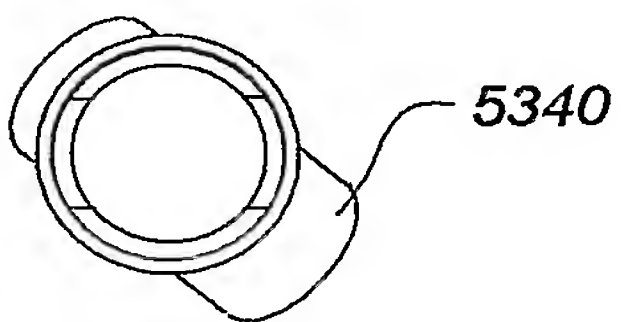


Fig - 53F

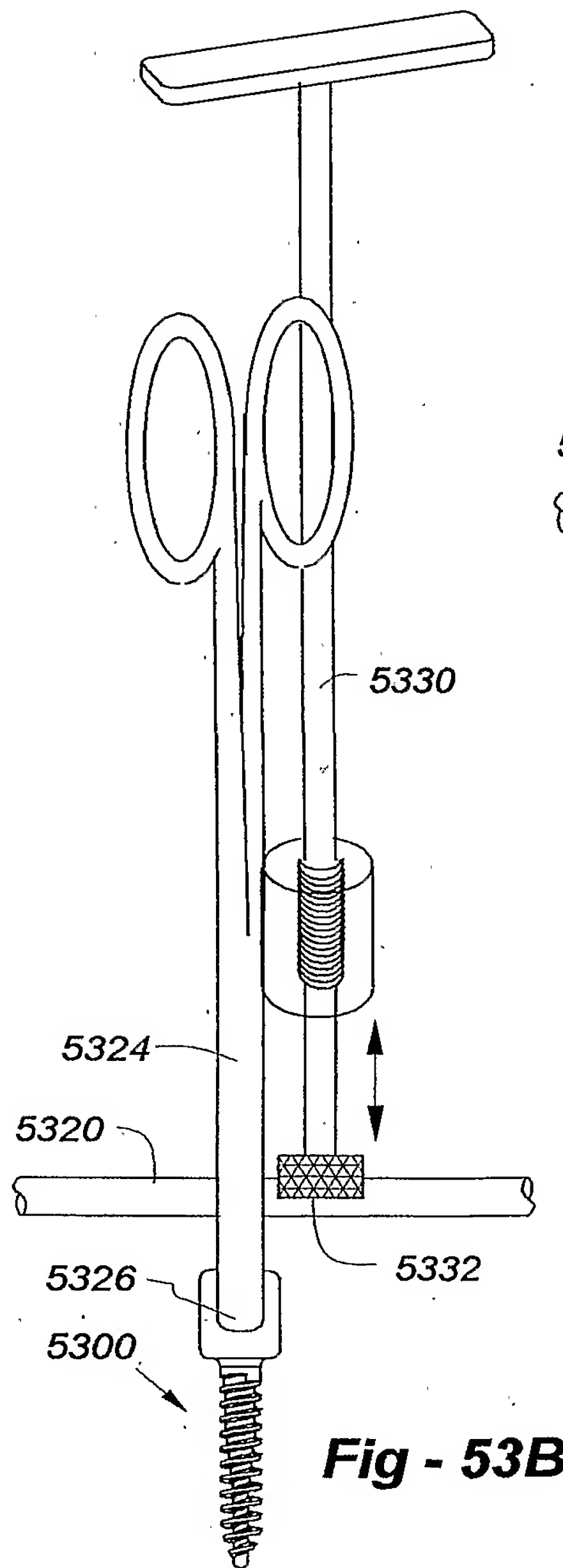


Fig - 53B

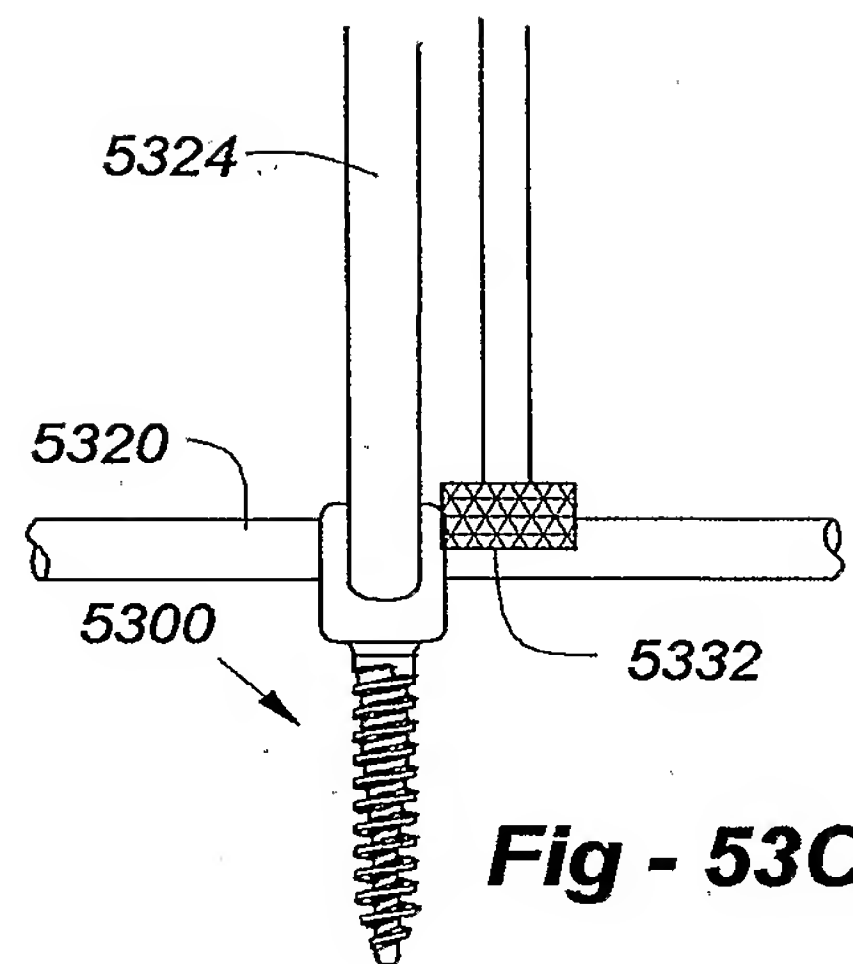


Fig - 53C

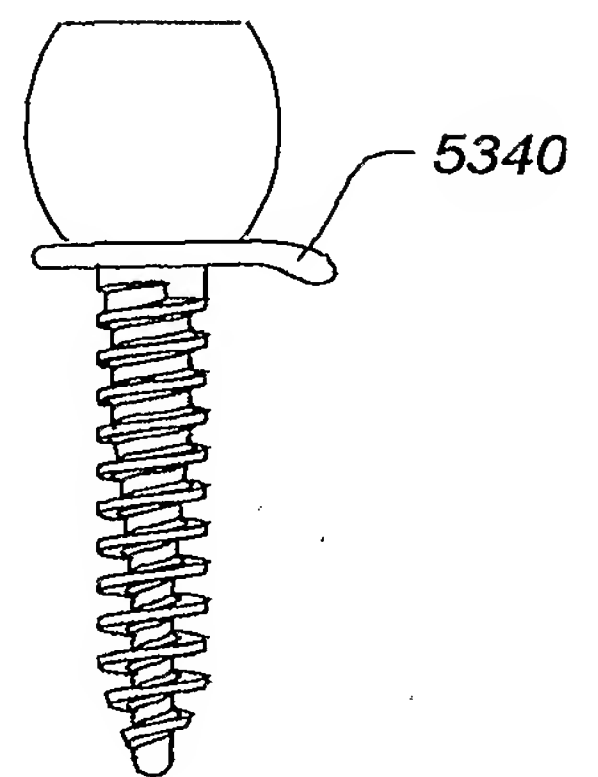


Fig - 53D

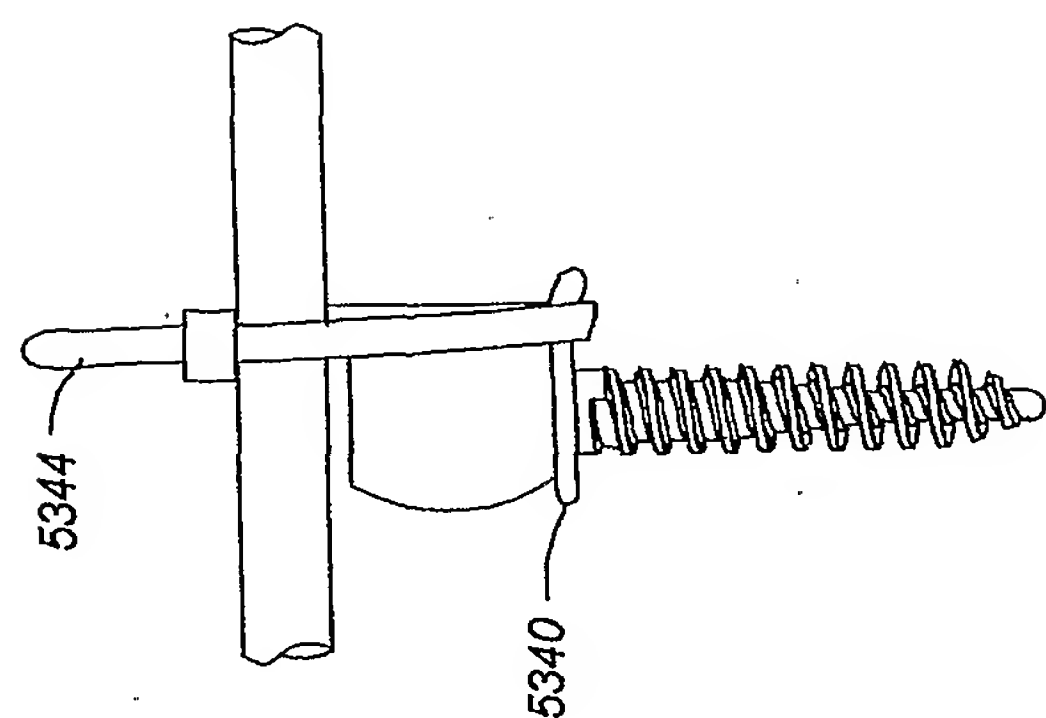


Fig - 53G

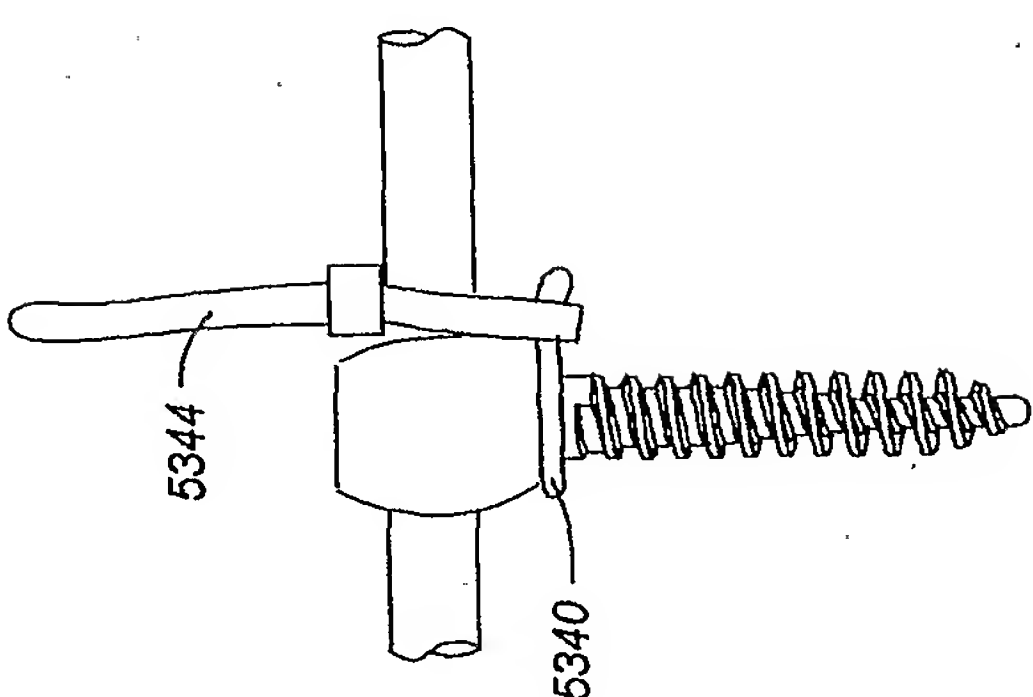


Fig - 53H

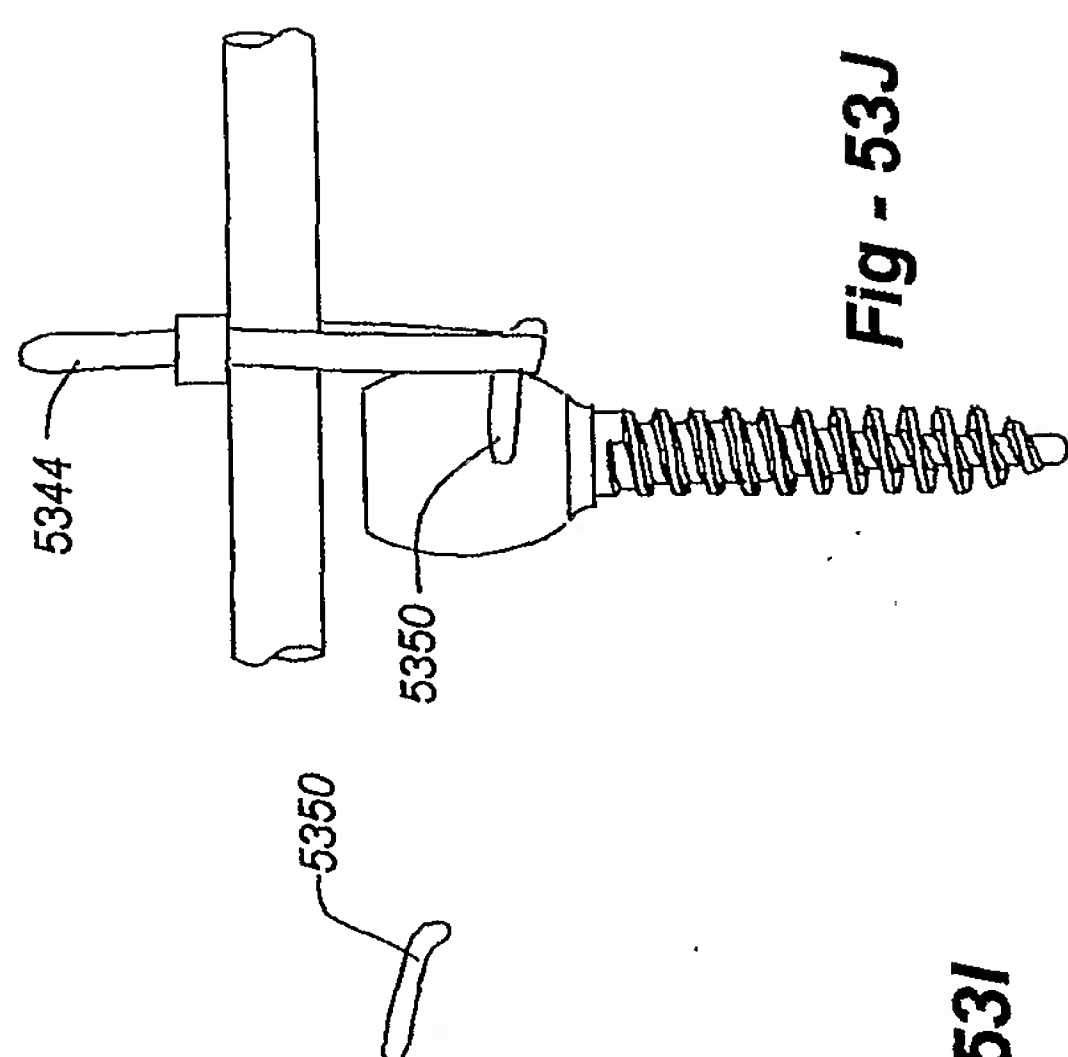


Fig - 53J



Fig - 53I

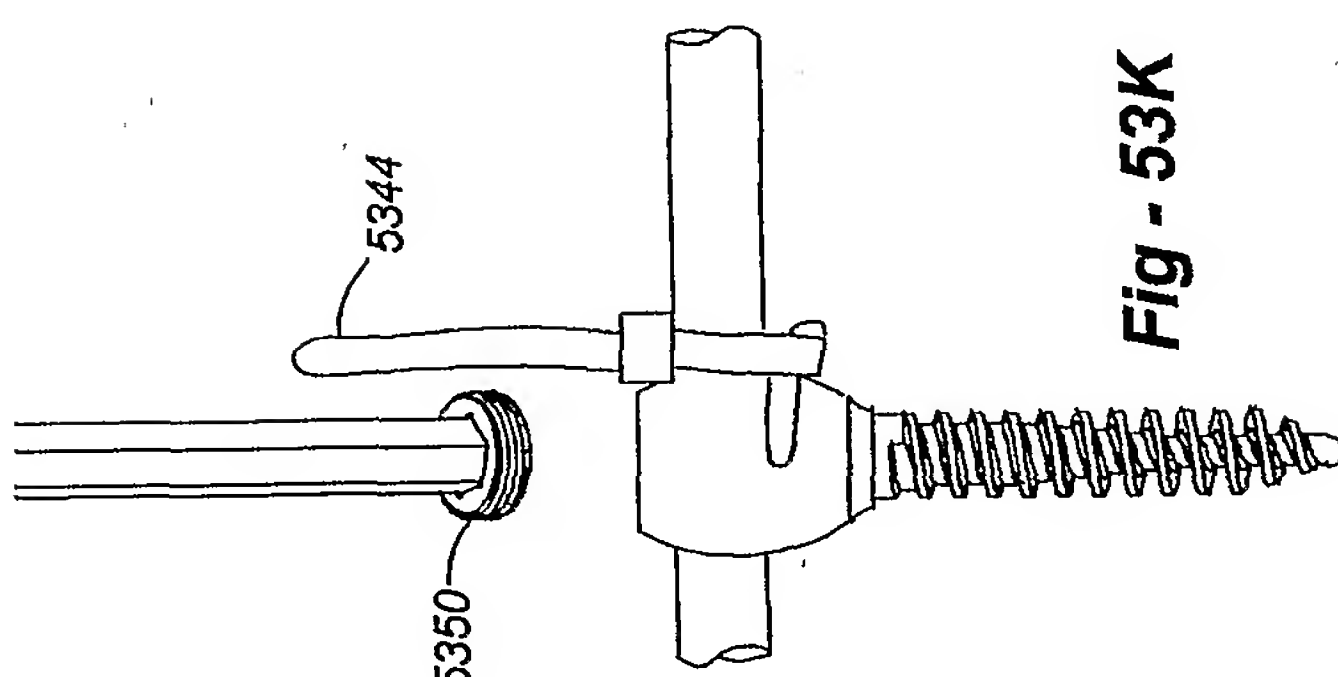


Fig - 53K

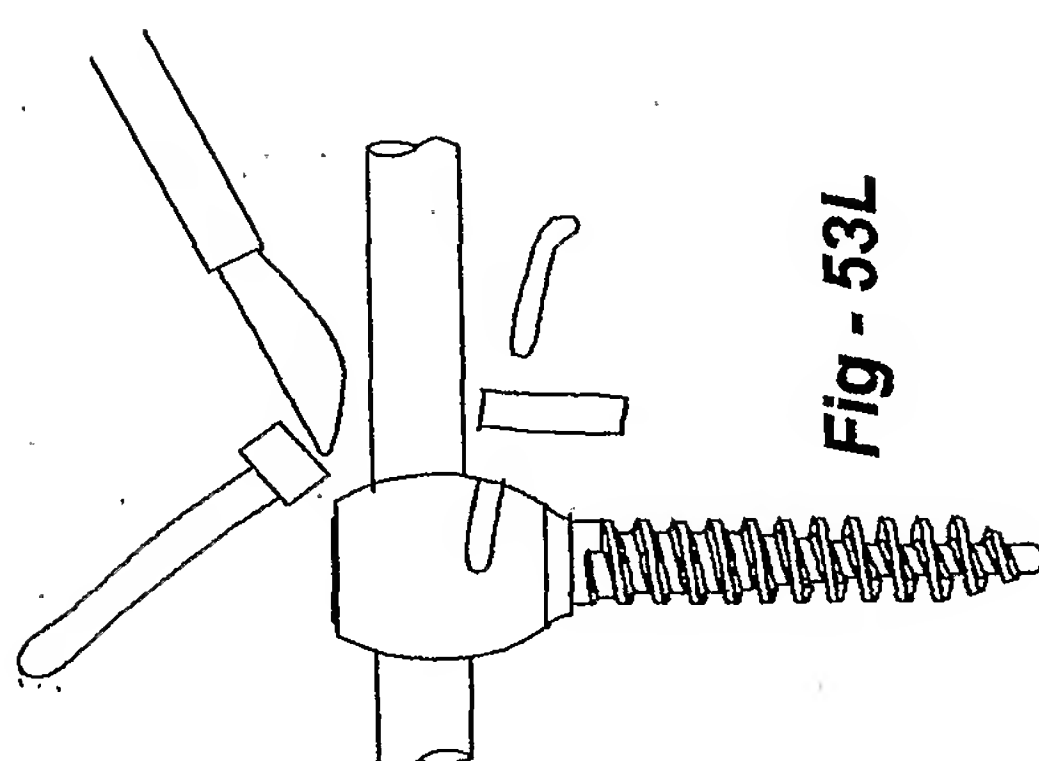


Fig - 53L

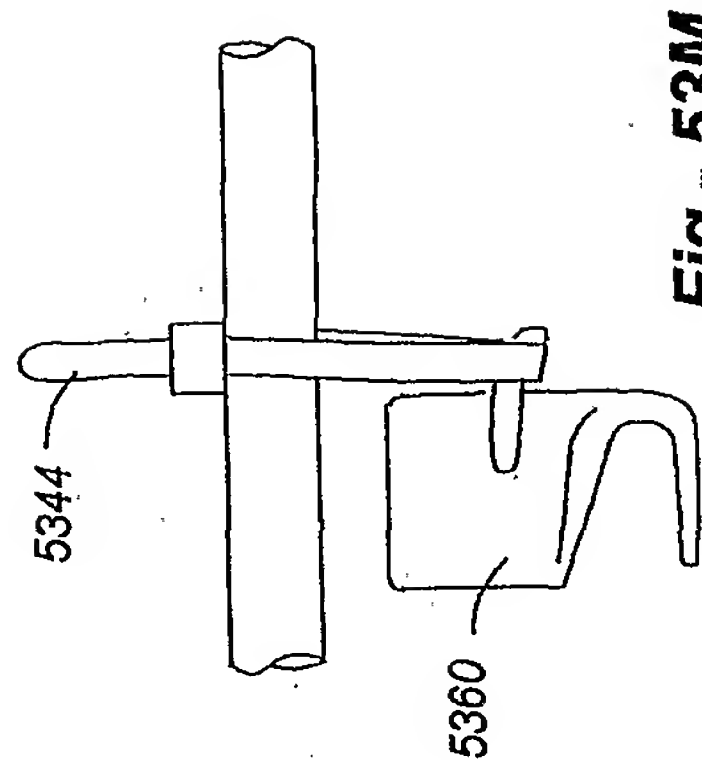


Fig - 53M

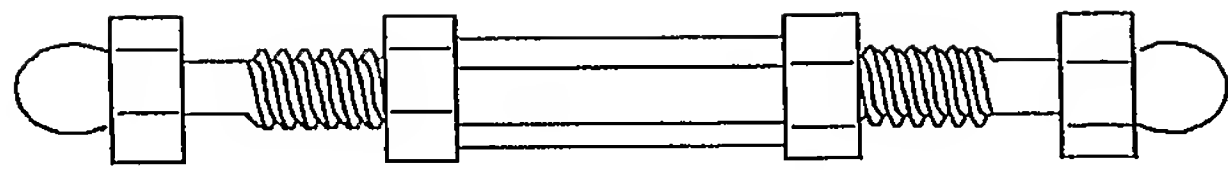


Fig - 54

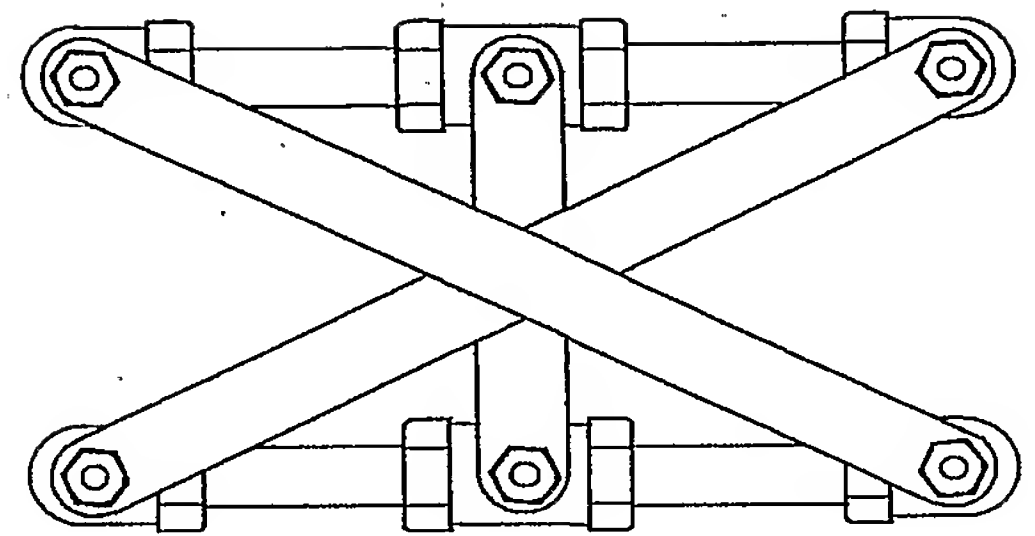


Fig - 55

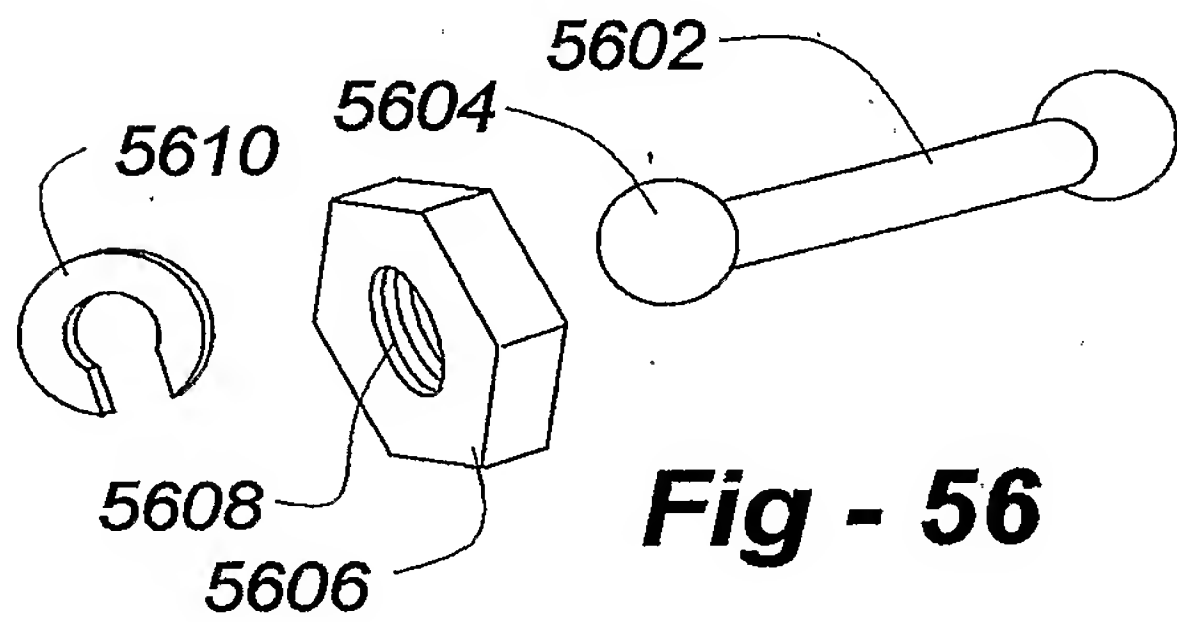


Fig - 56

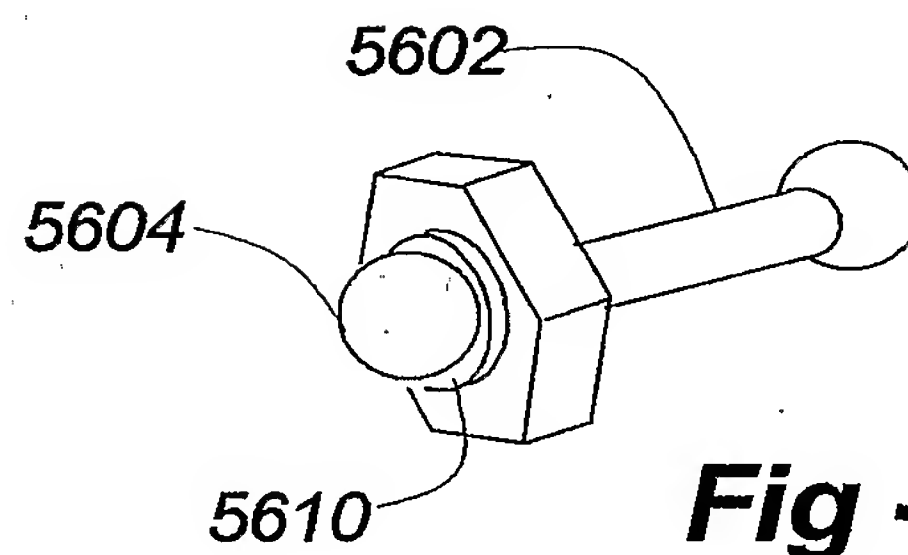


Fig - 57

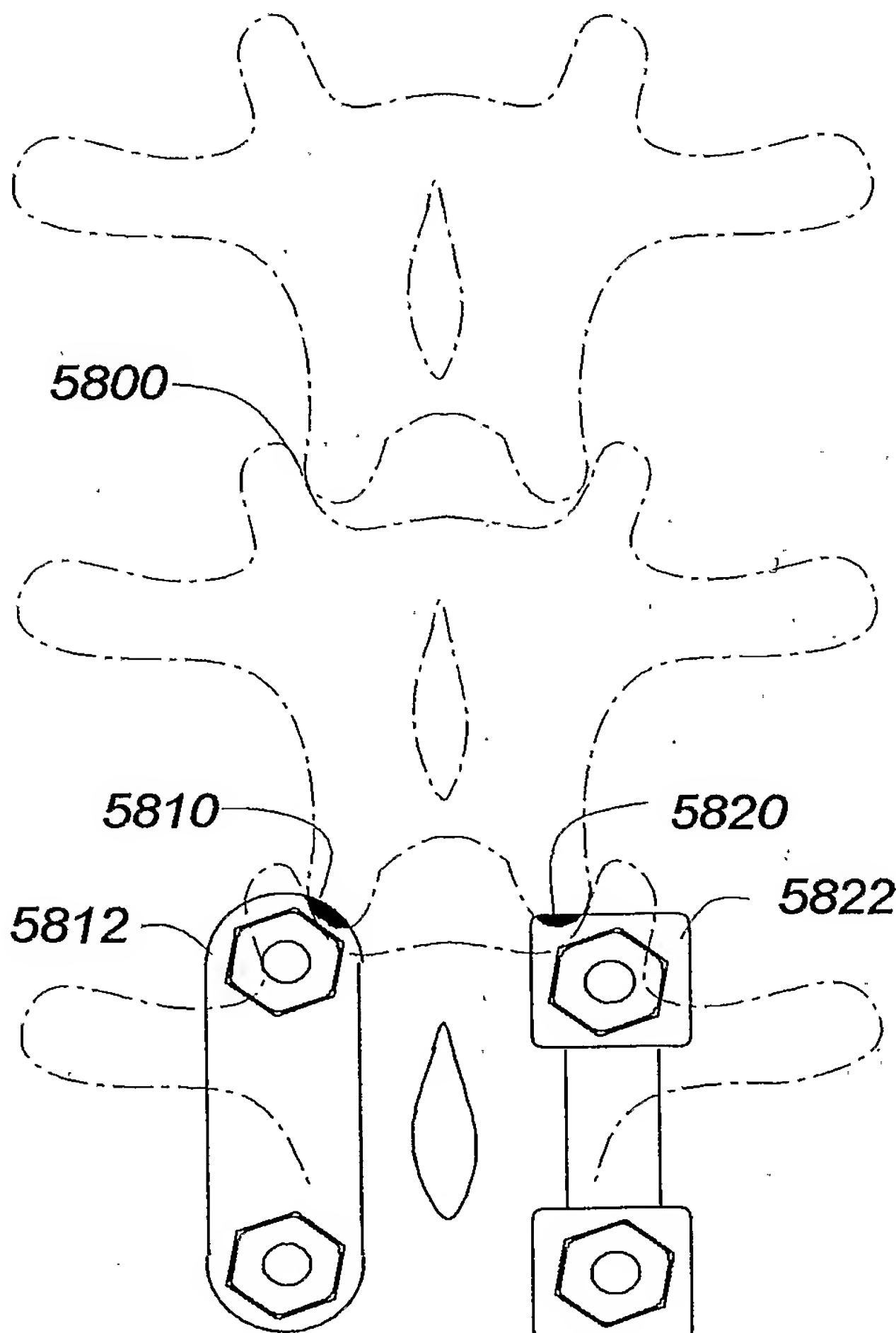


Fig - 58A

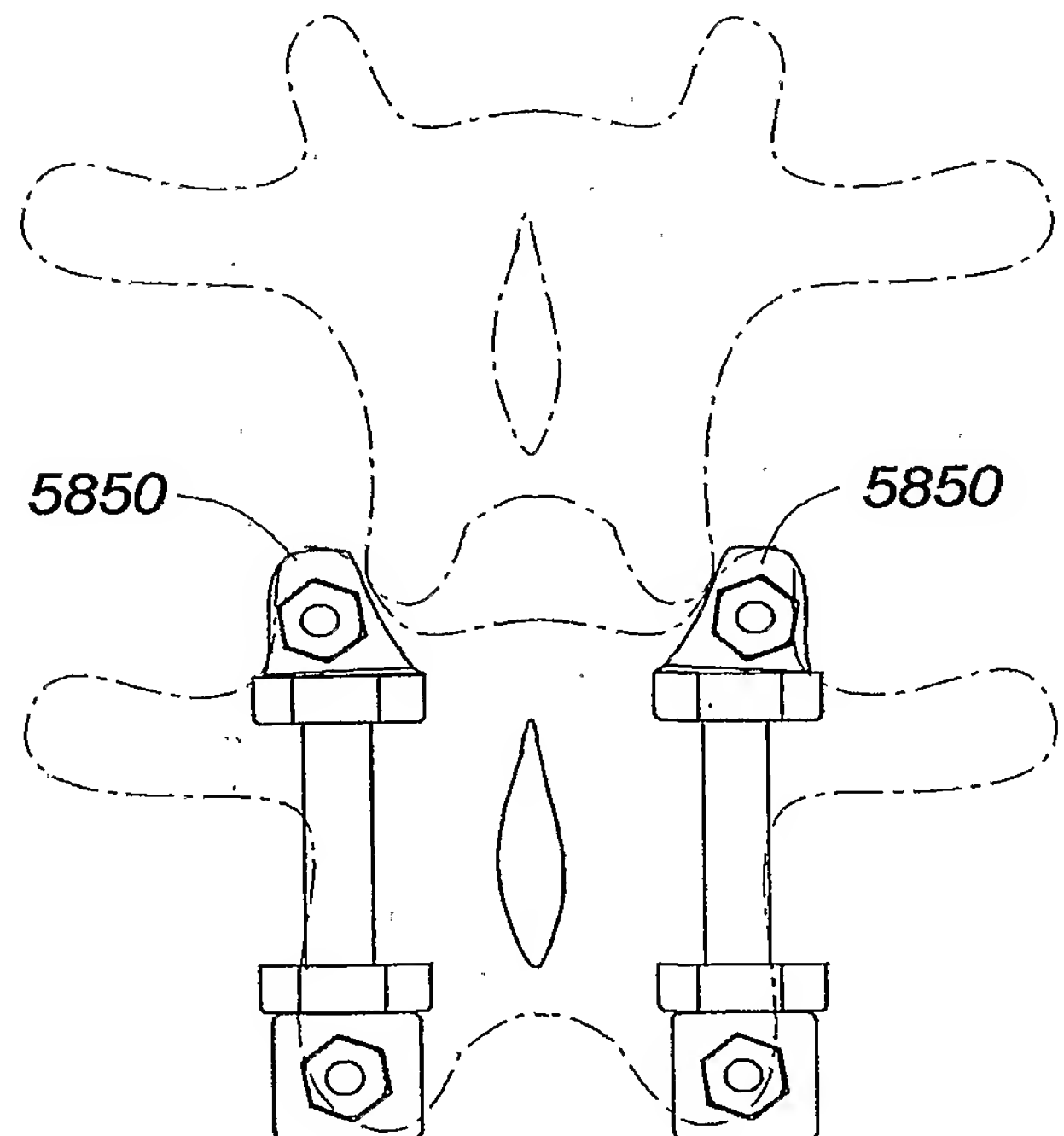


Fig - 58B

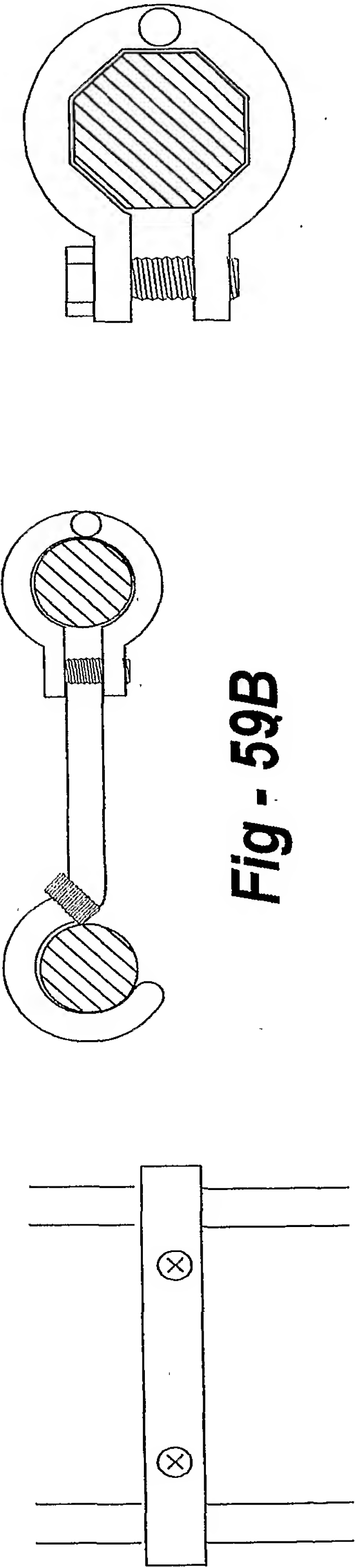
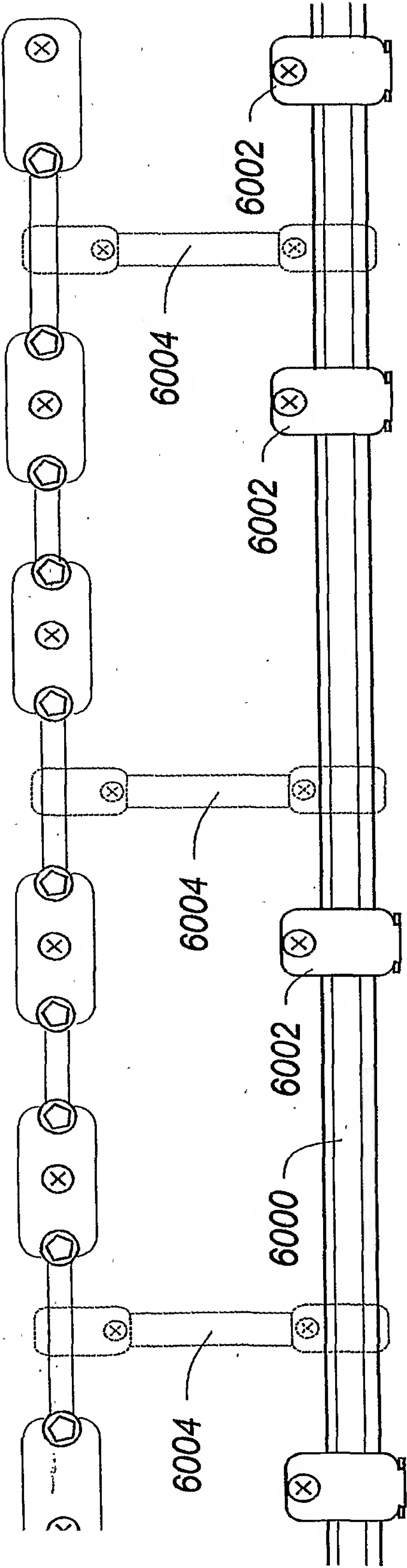


Fig - 61

Fig - 60



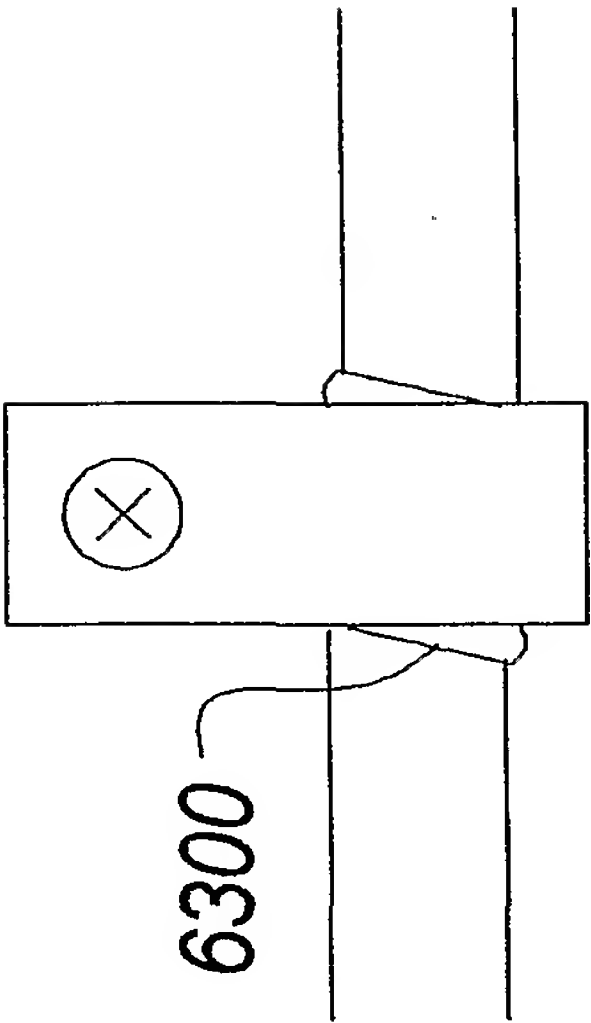


Fig - 63



Fig - 62A



Fig - 62B

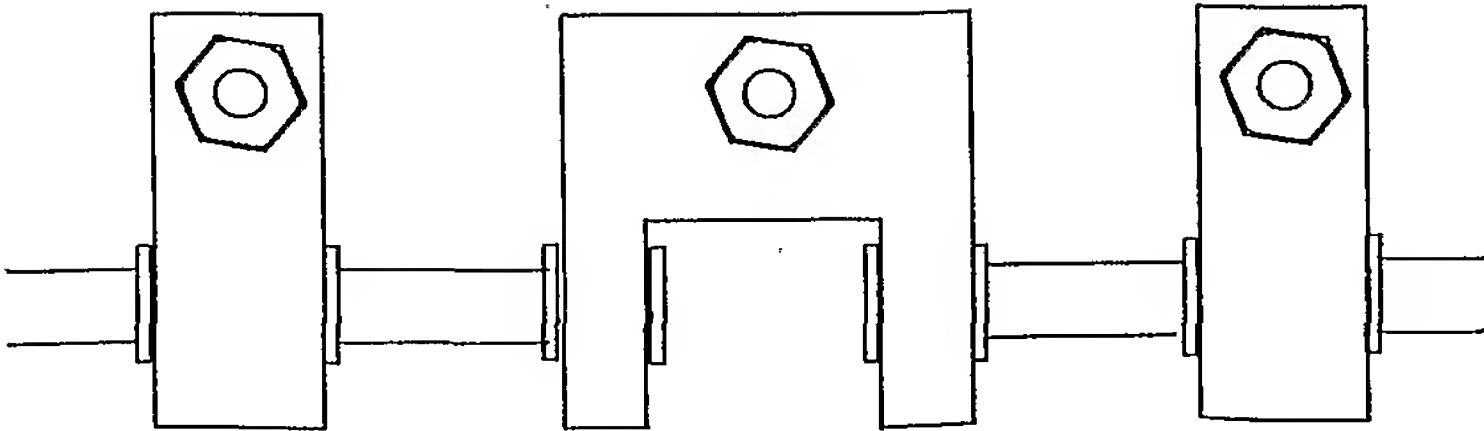


Fig - 64

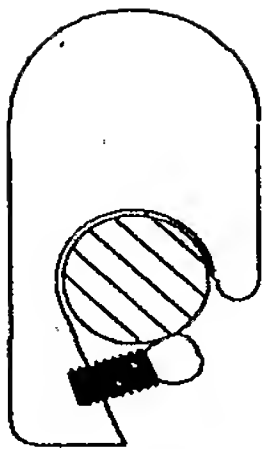


Fig - 65B

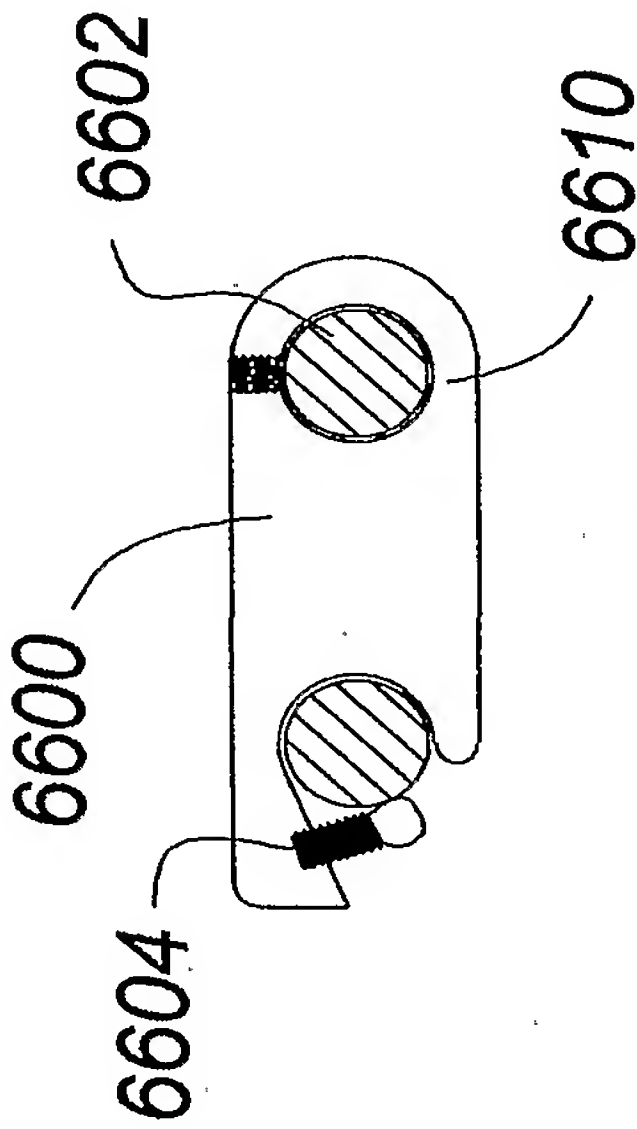


Fig - 66B

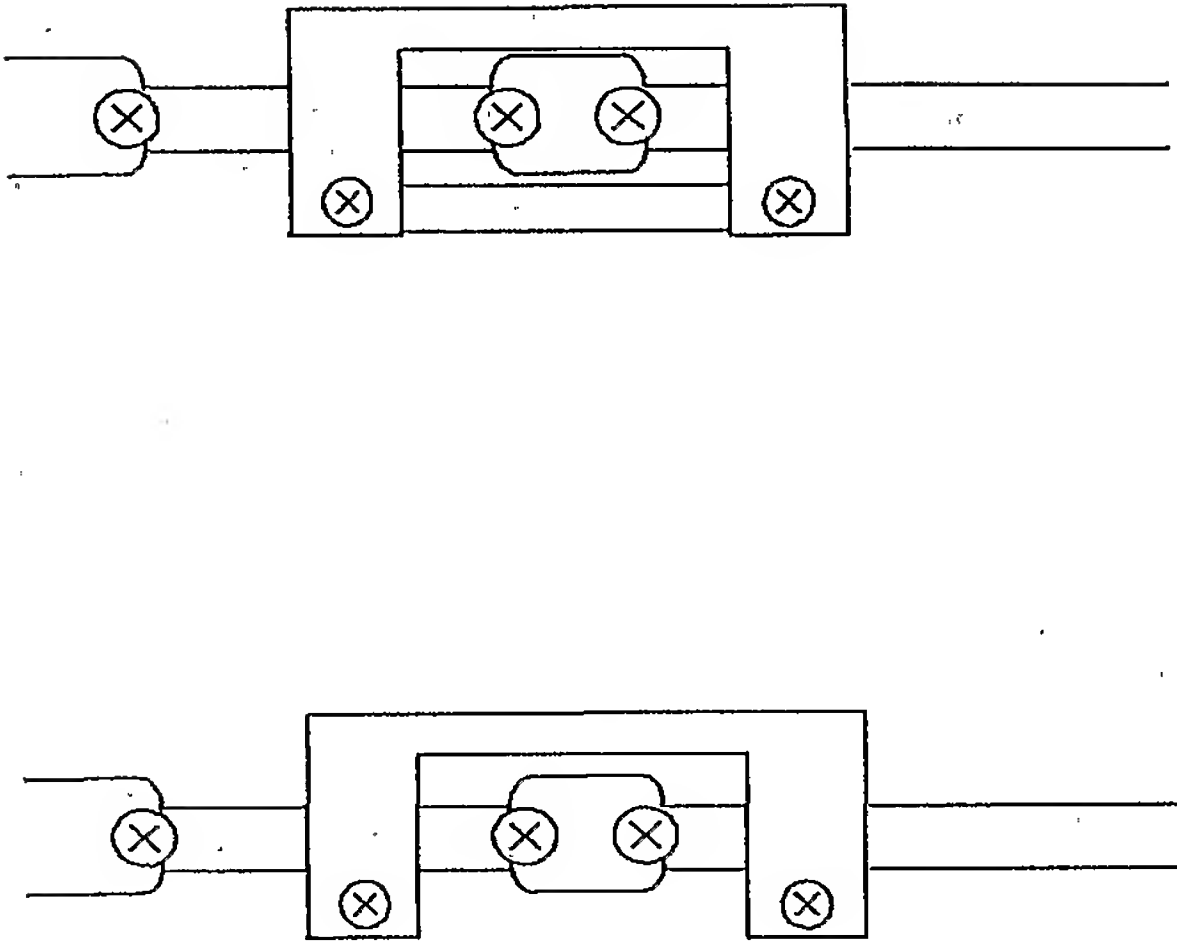


Fig - 66A

Fig - 65A

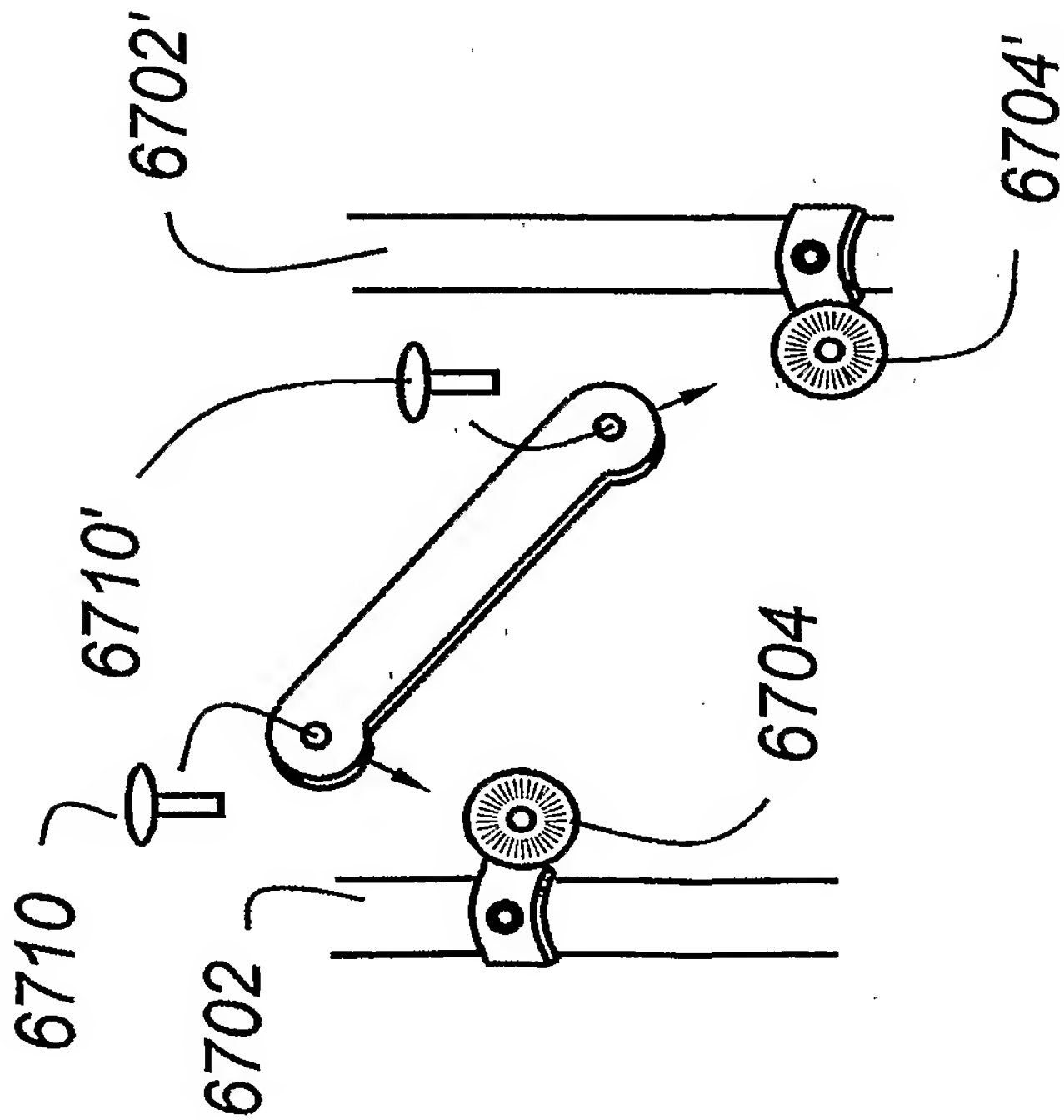


Fig - 67A

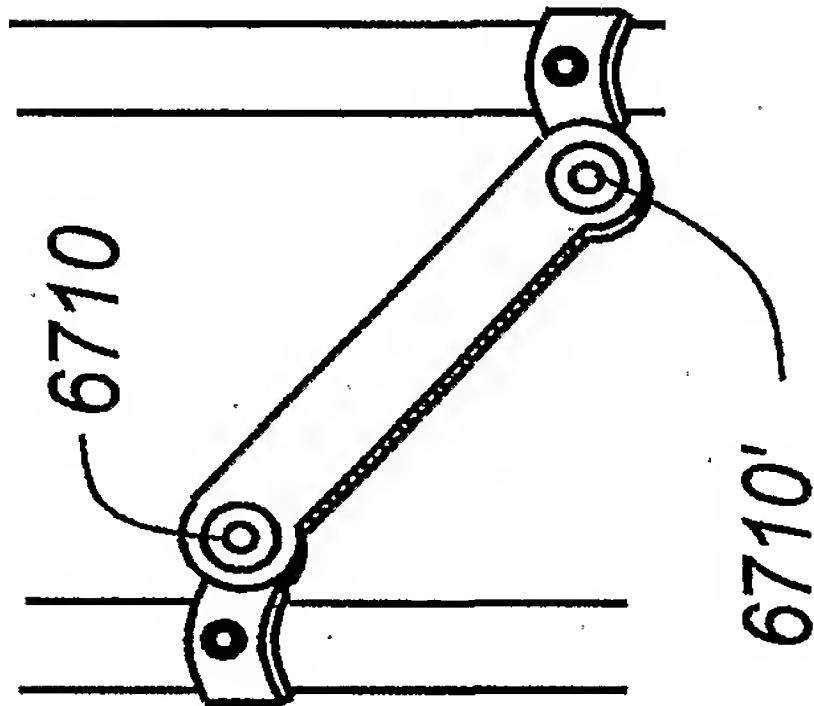


Fig - 67B

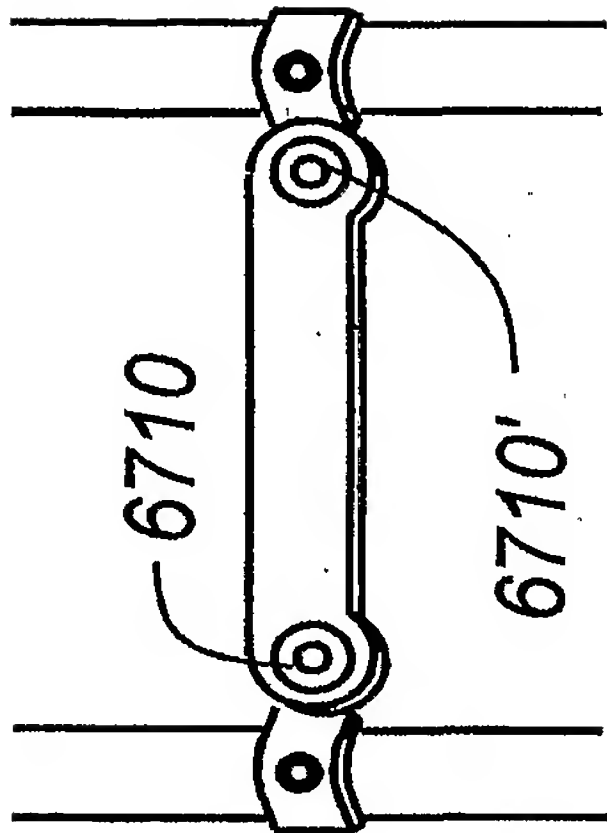


Fig - 67C

INTERNATIONAL SEARCH REPORT

Int ional Application No
PCT/US 02/11301

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B17/70

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EP0-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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A	the whole document	19
X	EP 1 072 228 A (DEV S E D SOC ET ;MULTI POLES CONSEILS (FR)) 31 January 2001 (2001-01-31)	1,2,4, 14-16,22
A	the whole document	7-10,13, 25
X	DE 38 41 008 A (ULRICH HEINRICH) 7 June 1990 (1990-06-07)	1,2,4, 14,16,22
A	the whole document	7-10,13, 25
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☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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Date of the actual completion of the international search

19 July 2002

Date of mailing of the international search report

29/07/2002

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Vere1st, P

INTERNATIONAL SEARCH REPORT

In International Application No

PCT/US 02/11301

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

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Information on patent family members

International Application No

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